

Standard Commercial
Prior Authorization Guidelines

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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1. **Formulary Agents**
   Drug products that are listed in the Formulary as Prior Authorization (PA) require evaluation, per MedImpact Pharmacy and Therapeutics Committee guidelines, when the member presents a prescription to a network pharmacy. Each request will be reviewed on individual patient need. If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
2. **Non-Formulary Agents**
   Any product not found in the Formulary listing, or any Formulary updates published by MedImpact**,** shall be considered a Non-Formulary drug. Coverage for non-formulary agents may be applied for in advance. When a member gives a prescription order for a non-formulary drug to a pharmacist, the pharmacist will evaluate the patient's drug history and contact the physician to determine if there is a legitimate medical need for a non-formulary drug. Each request will be reviewed on individual patient need. The following basic criteria are used:
   a. The use of Formulary Drug Products is contraindicated in the patient.
   b. The patient has failed an appropriate trial of Formulary or related agents.
   c. The choices available in the Drug Formulary are not suited for the present patient care need, and the drug selected is required for patient safety.
   d. The use of a Formulary drug may provoke an underlying condition, which would be detrimental to patient care.

   If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
3. **Obtaining Coverage**
   Coverage may be obtained by:
   a. Faxing a completed **Medication Request Form** to MedImpact at (858) 790-7100.
   b. Contacting MedImpact at (800) 788-2949 and providing all necessary information requested.

   MedImpact will provide an authorization number, specific for the medical need, for all approved requests. Non-approved requests may be appealed. The prescriber must provide information to support the appeal on the basis of medical necessity.

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ABALOPARATIDE

Generic	Brand				
ABALOPARATIDE	TYMLOS				

GUIDELINES FOR USE

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:
The request is for ONE of the following:
- Postmenopausal osteoporosis (a type of bone condition)
- To increase bone density in a male patient with osteoporosis (a type of bone condition)

If you have postmenopausal osteoporosis, approval also requires:
- You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
- You meet ONE of the following (a, b, or c):
  - You are at high risk for fractures defined as ONE of the following:
    - You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
    - You have TWO or more risk factors for a fracture such as a history of multiple recent low trauma fractures, bone mineral density (BMD) T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, or use of GnRH (gonadotropin-releasing hormone) analogs such as Synarel (nafarelin)
    - You have had no prior treatment for osteoporosis, AND you have a FRAX (Fracture Risk Assessment Tool: a type of test) score of at least 20% for any major fracture OR at least 3% for a hip fracture
  - You are unable to use oral therapy due to upper gastrointestinal (GI: stomach and intestine) problems (unable to tolerate oral medication), lower GI problems (unable to absorb oral medications), or trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate]) with other oral medications or in your daily routine
  - You have tried, have an intolerance to (side effect), or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

If the request is to increase bone density in a male patient with osteoporosis, approval also requires:

You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])

You meet ONE of the following (a or b):

You are at high risk for fractures defined as ONE of the following:

You have a history of osteoporotic fracture (a type of complete or partial break in a bone, such as fragility [weakness] fracture, low trauma [injury] fracture)

You have multiple risk factors for fracture (such as a history of multiple recent low trauma fractures, bone mineral density [BMD] T-score [a type of lab test] less than or equal to -2.5, corticosteroid use, use of GnRH [gonadotropin-releasing hormone] analogs such as Synarel [nafarelin])

You have failed or are intolerant (side effect) to other available osteoporosis therapy (such as Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

Effective: 02/01/26

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ABATACEPT - IV

Generic	Brand				
ABATACEPT/ MALTOSE	ORENCIA				

NOTE: For requests for the SQ dosage form of Orencia, please see the ABATACEPT - SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Prophylaxis (prevention) of acute graft versus host disease (aGVHD: a short-term type of immune disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

E. **If the request is for prophylaxis of acute graft versus host disease, approval also requires:**
   1. You are 2 years of age or older
   2. You are undergoing hematopoietic stem cell transplantation (HSCT: a type of cell transplantation) from a matched or one allele (version of a gene)-mismatched unrelated-donor
   3. Orencia will be used in combination with a calcineurin inhibitor (such as cyclosporine or tacrolimus) and methotrexate
   4. You will NOT use Orencia concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of acute graft versus host disease (a short-term type of immune disorder) prophylaxis (prevention)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ABATACEPT - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of acute graft versus host disease (aGVHD), please refer to the Initial Criteria section.

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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ABATACEPT - SQ

Generic	Brand				
ABATACEPT	ORENCIA, ORENCIA CLICKJECT				

NOTE: For requests for the IV dosage form of Orencia, please see the ABATACEPT - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard-of-care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Otezla (apremilast)
         iii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         iv. Tremfya (guselkumab)
         v. Skyrizi (risankizumab-rzaa)
         vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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INITIAL CRITERIA (CONTINUED)

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Taltz (ixekizumab)
   vii. Bimzelx (bimekizumab-bkzx)
   viii. Sotyktu (deucravacitinib)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ABATACEPT - SQ

RENEWAL CRITERIA

Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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RENEWAL CRITERIA (CONTINUED)

b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Otezla (apremilast)
   iii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Taltz (ixekizumab)
   vii. Bimzelx (bimekizumab-bkzx)
   viii. Sotyktu (deucravacitinib)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ABEMACICLIB

Generic	Brand			
ABEMACICLIB	VERZENIO			

GUIDELINES FOR USE

Our guideline named **ABEMACICLIB (Verzenio)** requires the following rule(s) be met for approval:

A. You have breast cancer
B. **If you have early breast cancer, approval also requires:**
   1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, node-positive (cancer that has spread to the lymph nodes)
   2. Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [such as letrozole, anastrozole, exemestane]) for adjuvant (add-on) treatment
   3. You are at high risk of recurrence (disease returning)
C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   2. You meet ONE of the following:
      a. Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, exemestane) as initial endocrine (hormone)-based therapy
      b. Verzenio will be used in combination with fulvestrant (Faslodex); AND you have experienced disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen)
      c. Verzenio will be used as monotherapy (one medication treatment); AND you have experienced disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen) as well as prior chemotherapy (drugs used to treat cancer) in the metastatic setting (cancer that has spread to other parts of the body)

Effective: 05/05/25

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ABIRATERONE

Generic	Brand				
ABIRATERONE ACETATE	ZYTIGA, ABIRTEGA, ABIRATERONE ACETATE				

GUIDELINES FOR USE

Our guideline named **ABIRATERONE (Zytiga, Abirtega)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   2. Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)
   3. Metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (cancer that has spread to other parts of the body and has not been treated with, or may respond to, testosterone-lowering treatment)

B. **If you have metastatic castration-resistant prostate cancer or metastatic high-risk castration-sensitive prostate cancer, approval also requires:**
   1. The requested medication will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
   2. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

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ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

C. **If you have metastatic androgen pathway modulation-naive or -sensitive prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used in combination with Truqap (capivasertib) and prednisone
   3. Your prostate cancer is PTEN-deficient (loss of a type of gene) as detected by a Food and Drug Administration (FDA)-authorized test
   4. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Effective: 07/08/26

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ABIRATERONE SUBMICRONIZED

Generic	Brand				
ABIRATERONE ACET, SUBMICRONIZED	YONSA				

GUIDELINES FOR USE

Our guideline named **ABIRATERONE SUBMICRONIZED (Yonsa)** requires the following rule(s) be met for approval:

You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

Yonsa will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)

You have tried or have a contraindication to (harmful for you to use) the preferred medication: Zytiga (abiraterone acetate)

You meet ONE of the following:

- You had a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- Yonsa will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Effective: 02/12/26

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ABOBOTULINUM TOXIN A (NSA)

Generic	Brand				
ABOBOTULINUM TOXIN A	DYSPORT				

GUIDELINES FOR USE

Our guideline named **ABOBOTULINUM TOXIN A (Dysport)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
Cervical dystonia (a type of muscle condition)
Spasticity (stiffness or tightness of your muscles)
If you have cervical dystonia, approval also requires:
You are 18 years of age or older
If you have spasticity, approval also requires:
You are 2 years of age or older

NOTE: This medication will not be approved for a cosmetic indication (for example wrinkles - glabellar lines, lateral canthal lines, forehead lines).

Effective: 11/01/22

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ABROCITINIB

Generic	Brand				
ABROCITINIB	CIBINQO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for approval:

A. You have refractory (did not respond to treatment), moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
E. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)
F. You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ABROCITINIB

RENEWAL CRITERIA

Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for renewal:

A. You have refractory (did not respond to treatment), moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You have shown improvement while on Cibinqo
C. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)
D. You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ACALABRUTINIB

Generic	Brand				
ACALABRUTINIB	CALQUENCE				
ACALABRUTINIB MALEATE	CALQUENCE				

GUIDELINES FOR USE

Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:
You have ONE of the following:
- Mantle cell lymphoma (MCL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Small lymphocytic lymphoma (SLL: a type of blood cancer)
- A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

If you have untreated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- Calquence will be used in combination with bendamustine and rituximab
- You are NOT eligible for autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

If you have previously treated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received at least one prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
- You are 18 years of age or older

Effective: 02/09/26

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ACETAMINOPHEN DAILY LIMIT OVERRIDE

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **ACETAMINOPHEN DAILY LIMIT OVERRIDE** will cause a denied claim for acetaminophen when the total daily dose acetaminophen exceeds 4000mg. The claim will also deny if the requested drug is being used at the same time with other acetaminophen containing product(s) and the combination exceeds 4000mg of acetaminophen per day limit.

Approval requires the following rule be met:

A. You will discontinue the other acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg.

Effective: 05/01/20

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ACNE AGE RESTRICTION OVERRIDE

Generic	Brand				
ADAPALENE	DIFFERIN, ADAPALENE				
TRETINOIN	ALTRENO				
TAZAROTENE	TAZAROTENE, TAZORAC				
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP, TRETINOIN MICROSPHERES				
TRIFAROTENE	AKLIEF				

GUIDELINES FOR USE

Our guideline named **ACNE AGE RESTRICTION OVERRIDE** requires the following rule(s) be met for approval:

A. The request is for a non-cosmetic (not for appearance) diagnosis (such as melasma [freckle-like spots on skin, photoaging [skin damage from the sun], wrinkles)
B. You had a trial of TWO low cost, clinical standard of care generic medications (such as adapalene lotion, cream or gel, tretinoin cream or gel, adapalene/benzoyl peroxide gel)

Effective: 07/01/26

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ACORAMIDIS

Generic	Brand				
ACORAMIDIS HCL	ATTRUBY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
D. You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
E. You will NOT use Attruby concurrently (at the same time) with a transthyretin stabilizer (tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)
F. Your diagnosis is confirmed by ONE of the following:
    1. A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)
    2. A biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

RENEWAL CRITERIA

Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for renewal:

A. You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You will NOT use Attruby concurrently (at the same time) with a transthyretin stabilizer (tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)

Effective: 06/10/26

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ADAGRASIB

Generic	Brand				
ADAGRASIB	KRAZATI				

GUIDELINES FOR USE

Our guideline named **ADAGRASIB (Krazati)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
   2. Locally advanced or metastatic colorectal cancer (CRC: a type of digestive tract cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)

B. **If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
   3. You have received at least one prior systemic therapy

C. **If you have locally advanced or metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
   3. Krazati will be used in combination with Erbitux (cetuximab)
   4. You have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (drugs used to treat cancer)

Effective: 08/01/24

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ADALIMUMAB-AATY

Generic	Brand				
ADALIMUMAB-AATY	ADALIMUMAB-AATY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB-AATY (Yuflyma)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to adalimumab-aaty
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

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INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin disorder)

J. **If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)
   4. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
   5. If you have non-infectious posterior uveitis (a type of eye condition), approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a glucocorticoid (such as methylprednisolone, prednisone), a systemic antimetabolite (such as methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

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ADALIMUMAB-AATY

RENEWAL CRITERIA

Our guideline named **ADALIMUMAB-AATY (Yuflyma)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   2. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

G. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

H. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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ADALIMUMAB-AATY

RENEWAL CRITERIA (CONTINUED)

I. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement in your hidradenitis suppurativa symptoms
   2. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

J. **If you have non-infectious intermediate, posterior, and panuveitis, renewal also requires:**
   1. You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
   2. You have maintained quiescence (inactive disease) OR have improved or maintained symptomatic improvement (such as eye redness, pain, photophobia [sensitivity to light], floaters, blurred vision)

Effective: 07/01/26

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ADALIMUMAB-ADAZ

Generic	Brand				
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB-ADAZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   2. Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

B. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

C. **If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)
   4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
   5. If you have non-infectious posterior uveitis (a type of eye condition), approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a glucocorticoid (such as methylprednisolone, prednisone), a systemic antimetabolite (such as methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA

Our guideline named **ADALIMUMAB-ADAZ** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   2. Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

B. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

C. **If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
   2. You have maintained quiescence (inactive disease) OR have improved or maintained symptomatic improvement (such as eye redness, pain, photophobia [sensitivity to light], floaters, blurred vision)

Effective: 07/01/26

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ADALIMUMAB-RYVK

Generic	Brand				
ADALIMUMAB-RYVK	ADALIMUMAB-RYVK				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB-RYVK (Simlandi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to adalimumab-ryvk
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

G. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

(Initial criteria continued on next page)

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

J. **If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
   3. You do NOT have isolated anterior uveitis (a different type of eye inflammation)
   4. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
   5. If you have non-infectious posterior uveitis (a type of eye condition), approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a glucocorticoid (such as methylprednisolone, prednisone), a systemic antimetabolite (such as methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

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ADALIMUMAB-RYVK

RENEWAL CRITERIA

Our guideline named **ADALIMUMAB-RYVK (Simlandi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   6. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   7. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   8. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
   9. Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   2. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

G. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

H. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

I. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement in your hidradenitis suppurativa symptoms
   2. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

(Renewal criteria continued on next page)

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

J. **If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:**
   1. You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
   2. You have maintained quiescence (inactive disease) OR have improved or maintained symptomatic improvement (such as eye redness, pain, photophobia [sensitivity to light], floaters, blurred vision)

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ADAMTS13 RECOMBINANT-KRHN

Generic	Brand				
ADAMTS13, RECOMBINANT-KRHN	ADZYNMA				

GUIDELINES FOR USE

Our guideline named **ADAMTS13 RECOMBINANT-KRHN (Adzynma)** requires the following rule(s) be met for approval:

A. You have congenital thrombotic thrombocytopenic purpura (cTTP: a type of blood disorder)

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ADAPALENE-BENZOYL-CLINDAMYCIN

Generic	Brand				
ADAPALENE/BENZOYL/ CLINDAMYCIN	CABTREO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for approval:

A. You have acne vulgaris (a type of skin condition usually called pimples)
B. You are 12 years of age or older
C. Cabtreo will NOT be used at the same time with other acne therapies that are only available as brand name (such as Aklief, Winlevi)
D. You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication in EACH of the following categories:
    1. Benzoyl peroxide product
    2. Topical retinoid (such as adapalene, tretinoin)
    3. Topical antibiotic (such as clindamycin, erythromycin)

RENEWAL CRITERIA

Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for renewal:

A. You have acne vulgaris (a type of skin condition usually called pimples)
B. You have shown improvement in your acne symptoms (the treatment is working)
C. Cabtreo will NOT be used at the same time with other acne therapies that are only available as brand name (such as Aklief, Winlevi)

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ADO-TRASTUZUMAB EMTANSINE

Generic					
ADO-TRASTUZUMAB EMTANSINE					

GUIDELINES FOR USE

Our guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires the following rule(s) be met for approval:
You have breast cancer
If you have metastatic breast cancer (cancer that has spread to other parts of the body), approval also requires:
Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
You have previously received trastuzumab and a taxane (such as docetaxel, paclitaxel)
You have received prior therapy for metastatic disease OR have developed disease recurrence (disease has returned) during or within 6 months of completing adjuvant (add-on) therapy
If you have early breast cancer (cancer has not spread to other parts of the body), approval also requires:
Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
You have residual (remaining) invasive disease after neoadjuvant (given before main treatment) taxane and trastuzumab-based treatment (types of cancer treatment)

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ADUCANUMAB-AVWA (NSA)

Generic	Brand				
ADUCANUMAB-AVWA	ADUHELM				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADUCANUMAB-AVWA (Aduhelm)** requires the following rule(s) be met for approval:

You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease

Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), geriatrician (a doctor who specializes in the health care of elderly individuals), or psychiatrist (a type of mental health doctor)

You have the presence of amyloid-beta plaques (an indicator of Alzheimer's disease)

You have a Clinical Dementia Rating (CDR: a tool for evaluating memory loss) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE: a test used to evaluate memory, thinking, and understanding) score of 24 to 30

MRI (magnetic resonance imaging) within one year prior to treatment

You do NOT have a history of a clotting disorder (condition that interferes with the blood’s ability to clot)

You are participating in an FDA (Federal Drug Administration)/NIH (National Institute of Health) approved clinical trial

You are NOT concurrently (at the same time) using any anticoagulant or antiplatelet therapy (such as Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

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ADUCANUMAB-AVWA (NSA)

RENEWAL CRITERIA

Our guideline named **ADUCANUMAB-AVWA (Aduhelm)** requires the following rule(s) be met for renewal:

You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease

Your cognitive decline has slowed or stopped

You are NOT experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA: abnormal differences seen on magnetic resonance imaging [MRI: a type of imaging] of the brain)

You are NOT concurrently (at the same time) using any anticoagulant or antiplatelet therapy, (such as Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

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AFAMELANOTIDE

Generic	Brand				
AFAMELANOTIDE ACETATE	SCENESSE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AFAMELANOTIDE (Scenesse)** requires the following rule(s) be met for approval:

A. You have erythropoietic protoporphyria (EPP: a rare disorder that makes exposure to light extremely painful)
B. You are 18 years of age or older
C. You have a history of phototoxic reactions (damage to the skin)
D. Scenesse will be used to increase pain free light exposure
E. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor) or hematologist (a type of blood doctor)
F. You have an elevated (higher than normal) total erythrocyte protoporphyrin (a type of lab test) that is greater than 3 times the upper limit of normal (ULN) AND the majority of protoporphyrin (a type of substance in the body) is metal-free

RENEWAL CRITERIA

Our guideline named **AFAMELANOTIDE (Scenesse)** requires the following rule(s) be met for renewal:

A. You have erythropoietic protoporphyria (EPP: a rare disorder that makes exposure to light extremely painful)
B. You have shown a positive clinical response in phototoxic reactions (damage to the skin)

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AFATINIB

Generic	Brand				
AFATINIB DIMALEATE	GILOTRIF				

GUIDELINES FOR USE

Our guideline named **AFATINIB (Gilotrif)** requires the following rule(s) be met for approval:
You have non-small cell lung cancer (NSCLC: type of lung cancer)

If you have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body), approval also requires:
Your tumor has a non-resistant epidermal growth factor receptor (EGFR: type of protein) mutation as shown by an FDA (Food and Drug Administration)-approved test
You will NOT use Gilotrif concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

If you have metastatic squamous non-small cell lung cancer (cancer began in the squamous cells of the lung and has spread to other parts of the body), approval also requires:
Your disease has progressed (worsened) after using platinum-based chemotherapy (cisplatin, carboplatin, oxaliplatin)

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AFICAMTEN

Generic	Brand				
AFICAMTEN	MYQORZO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AFICAMTEN (Myqorzo)** requires the following rule(s) be met for approval:

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
D. You have New York Heart Association (NYHA) functional class II or III (a way to classify the severity of symptoms)
E. You have a peak left ventricular outflow tract (LVOT) gradient (evaluates the severity of disease) of at least 50 mmHg at rest or with provocation (a type of technique to evaluate how the heart performs under stress)
F. You will NOT use Myqorzo concurrently (at the same time) with another myosin inhibitor (such as Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)
G. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a beta-blocker (such as metoprolol, carvedilol), a non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem)
H. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Camzyos (mavacamten)

RENEWAL CRITERIA

Our guideline named **AFICAMTEN (Myqorzo)** requires the following rule(s) be met for renewal:

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You have experienced continued clinical benefit (such as reduction of symptoms, New York Heart Association [NYHA] classification [a way to classify severity of symptoms] improvement)
C. You will NOT use Myqorzo concurrently (at the same time) with another myosin inhibitor (such as Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)

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AFLIBERCEPT-AYYH

Generic	Brand				
AFLIBERCEPT-AYYH	PAVBLU				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AFLIBERCEPT-AYYH (Pavblu)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Retinopathy of prematurity (ROP: a type of eye condition in babies that are born early)

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll], Eylea [aflibercept])

If you have macular edema following retinal vein occlusion, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])

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INITIAL CRITERIA (CONTINUED)

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Eylea [aflibercept])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

RENEWAL CRITERIA

NOTE: For the diagnosis of retinopathy of prematurity (ROP), please refer to the Initial Criteria section.

Our guideline named **AFLIBERCEPT-AYYH (Pavblu)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll], Eylea [aflibercept])

If you have macular edema following retinal vein occlusion, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])

(Renewal criteria continued on next page)

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AFLIBERCEPT-AYYH

RENEWAL CRITERIA (CONTINUED)

If you have diabetic macular edema, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa]), Eylea [aflibercept])

If you have diabetic retinopathy, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Eylea [aflibercept])

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AFLIBERCEPT-EYLEA

Generic	Brand				
AFLIBERCEPT	EYLEA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AFLIBERCEPT-EYLEA** requires the following rule(s) be met for approval:
You have ONE of the following:
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Retinopathy of prematurity (ROP: a type of eye condition in babies that are born early)

If you have macular edema following retinal vein occlusion, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

RENEWAL CRITERIA

NOTE: For the diagnosis of retinopathy of prematurity (ROP), please refer to the Initial Criteria section.

Our guideline named **AFLIBERCEPT-EYLEA** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)

If you have macular edema following retinal vein occlusion, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If you have diabetic retinopathy, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])

If you have diabetic macular edema, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

(Renewal criteria continued on next page)

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AFLIBERCEPT-EYLEA

RENEWAL CRITERIA (CONTINUED)

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

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AFLIBERCEPT-EYLEA HD

Generic	Brand				
AFLIBERCEPT	EYLEA HD				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AFLIBERCEPT-EYLEA HD** requires the following rule(s) be met for approval:

You have ONE of the following:
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

(Initial criteria continued on next page)

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AFLIBERCEPT-EYLEA HD

INITIAL CRITERIA (CONTINUED)

If you have macular edema following retinal vein occlusion, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

RENEWAL CRITERIA

Our guideline named **AFLIBERCEPT-EYLEA HD** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)

If you have diabetic retinopathy, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])

If you have diabetic macular edema, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If you have macular edema following retinal vein occlusion, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

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AGALSIDASE BETA

Generic	Brand				
AGALSIDASE BETA	FABRAZYME				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for approval:

A. You have Fabry disease (a rare genetic disease)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor), cardiologist (a type of heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
D. You will NOT use Fabrazyme concurrently (at the same time) with another Fabry disease medication (such as Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])
E. You are symptomatic OR have evidence of injury from GL-3 (globotriaosylceramide: a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury may include decreased glomerular filtration rate (GFR: a tool for evaluating kidney function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (magnetic resonance imaging: type of imaging lab), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
F. **If you are a female, approval also requires:**
    1. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing
G. **If you are a male, approval also requires ONE of the following:**
    1. You do NOT have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
    2. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing

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AGALSIDASE BETA

RENEWAL CRITERIA

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for renewal:

A. You have Fabry disease (a rare genetic disease)
B. You will NOT use Fabrazyme concurrently (at the same time) with another Fabry disease medication (such as Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])
C. You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
    1. Symptoms (such as pain, hypohidrosis [less sweating]/anhidrosis [no sweating], exercise intolerance, GI [gastrointestinal] symptoms, angiokeratomas [dark red-blue raised spots on the skin], abnormal cornea [a part of the eye], tinnitus [ringing in the ears]/hearing loss)
    2. Imaging (such as brain/cardiac MRI [magnetic resonance imaging: type of imaging lab], DEXA [a type of bone scan], renal [kidney] ultrasound)
    3. Laboratory or histological (viewed by microscope) testing (such as GL-3 [globotriaosylceramide: a type of fat] in plasma/urine, renal biopsy [removal of cells or tissue from the body for examination])

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ALECTINIB

Generic	Brand				
ALECTINIB HCL	ALECENSA				

GUIDELINES FOR USE

Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:
You have non-small cell lung cancer (NSCLC: a type of lung cancer)
You are 18 years of age or older
Your cancer is anaplastic lymphoma kinase (ALK)-positive (a type of abnormal gene change), as detected by a Food and Drug Administration (FDA)-approved test
You meet ONE of the following:
- Your cancer is node positive (cancer has spread to the lymph nodes) or your tumor is at least 4 cm, and Alecensa will be used as adjuvant (additional) treatment following tumor resection (surgical removal of a tumor)
- Your cancer is metastatic (has spread to other parts of the body)

Effective: 02/01/26

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ALEMTUZUMAB

Generic	Brand				
ALEMTUZUMAB	LEMTRADA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for approval:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder) which includes relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

RENEWAL CRITERIA

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for renewal:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
At least 12 months have passed since you received the most recent course of Lemtrada

Effective: 01/01/26

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ALGLUCOSIDASE ALFA

Generic	Brand				
ALGLUCOSIDASE ALFA	LUMIZYME				

GUIDELINES FOR USE

Our guideline named **ALGLUCOSIDASE ALFA (Lumizyme)** requires the following rule(s) be met for approval:

A. You have Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)

Effective: 02/24/25

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ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand			
MITE,D.FARINAE-D.PTERONYSSINUS	ODACTRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites
B. You are 5 to 65 years of age
C. Your diagnosis is confirmed by in vitro testing (testing outside of the body in a tube) for IgE (immunoglobulin E) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, OR by skin testing to licensed house dust mite allergen extracts
D. Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, impairment of school or work)
G. You have a current claim or prescription for an auto-injectable epinephrine within the past 365 days

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) is met for renewal:

A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

Effective: 04/01/25

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

Generic	Brand				
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of the body in a tube) for pollen-specific IgE (immunoglobulin E) antibodies for any of the five grass types included in Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens)
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for auto-injectable epinephrine
You are 5 to 65 years of age

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

Effective: 02/01/26

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand				
WEED POLLEN-SHORT RAGWEED	RAGWITEK				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
You are 5 to 65 years of age
Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of the body in a tube) for pollen-specific IgE (immunoglobulin E) antibodies for short ragweed pollen
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis from baseline (before treatment)

Effective: 02/01/26

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Generic	Brand				
GRASS POLLEN-TIMOTHY, STD	GRASTEK				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
You are 5 to 65 years of age
Your diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for timothy grass or cross-reactive grass pollens
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate to severe symptoms of allergic rhinitis including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

Effective: 02/01/26

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ALPELISIB-PIQRAY

Generic	Brand				
ALPELISIB	PIQRAY				

GUIDELINES FOR USE

Our guideline named **ALPELISIB-PIQRAY** requires the following rule(s) be met for approval:
You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
Piqray will be used in combination with fulvestrant (Faslodex)
Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
Your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
You have disease progression (condition has worsened) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

Effective: 02/01/26

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ALPELISIB - VIJOICE

Generic	Brand				
ALPELISIB	VIJOICE				

GUIDELINES FOR USE

Our guideline named **ALPELISIB - VIJOICE** requires the following rule(s) be met for approval:
You have PIK3CA-related overgrowth spectrum (PROS: group of disorders that cause overgrowth of parts of the body due to mutations in a type of gene)
You are 2 years of age or older
You have severe manifestations of PROS that require systemic therapy (treatment that targets the entire body)

Effective: 10/01/22

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ALPHA-1-PROTEINASE INHIBITOR

Generic	Brand				
ALPHA-1-PROTEINASE INHIBITOR	GLASSIA, PROLASTIN C, ARALAST NP, ZEMAIRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALPHA-1-PROTEINASE INHIBITOR (Glassia, Prolastin C, Aralast NP, Zemaira)** requires the following rule(s) be met for approval:

You have clinically evident emphysema (a type of lung disease) due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin [AAT] deficiency) (a type of genetic condition)

You are 18 years of age or older

The requested medication will be used as chronic augmentation therapy (long-term replacement treatment) or maintenance therapy (taken on a regular basis)

Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)

Your alpha-1 antitrypsin deficiency genotype (a set of genes) does NOT include a normal M gene (such as MZ [a type of gene])

You have a forced expiratory volume (FEV1: amount of air exhaled in one second) of less than or equal to 65 percent

You are not currently smoking

You have a documented pre-treatment alpha1-antitrypsin (AAT: a type of protein) level of less than or equal to 57mg/dL or 11micromol/L

You do not have an IgA deficiency (a type of condition where the immune system does not make enough of a type of antibody)

You will NOT use the requested medication concurrently (at the same time) with another alpha-1-proteinase inhibitor (such as Glassia, Prolastin C, Aralast NP, Zemaira)

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ALPHA-1-PROTEINASE INHIBITOR

RENEWAL CRITERIA

Our guideline named **ALPHA-1-PROTEINASE INHIBITOR (Glassia, Prolastin C, Aralast NP, Zemaira)** requires the following rule(s) be met for renewal:

You have clinically evident emphysema (a type of lung disease) due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin [AAT] deficiency) (a type of genetic condition)

You have shown clinical benefit (improvement) (maintained or slowed progression of emphysema [a type of lung disease])

You are not currently smoking

You will NOT use the requested medication concurrently (at the same time) with another alpha-1-proteinase inhibitor (such as Glassia, Prolastin C, Aralast NP, Zemaira)

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AMANTADINE EXTENDED RELEASE

Generic	Brand				
AMANTADINE EXTENDED RELEASE	GOCOVRI				
AMANTADINE HCL	OSMOLEX ER				

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

GOCOVRI

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:
You have Parkinson's disease (type of movement disorder)
If you have dyskinesia (uncontrolled involuntary muscle movements), approval also requires:
You are receiving levodopa-based therapy
You have tried generic amantadine capsules, tablets, or solution
If you are experiencing 'off' episodes (period of symptoms in between doses), approval also requires:
Gocovri will be used as adjunctive (add-on) treatment to levodopa-carbidopa therapy
You have tried generic amantadine capsules, tablets, or solution

OSMOLEX ER

Our guideline named **AMANTADINE EXTENDED RELEASE (Osmolex ER)** requires the following rule(s) be met for approval:
You have one of the following:
Parkinson's disease (type of movement disorder)
Drug-induced extrapyramidal symptoms (group of movement disorders)
If you have Parkinson's disease, approval also requires:
Therapy is prescribed by or in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who specializes in treating older adults)
You have tried generic amantadine immediate-release capsules, tablets or solution
If you have drug-induced extrapyramidal symptoms, approval also requires:
You are 18 years of age or older
Therapy is prescribed by or in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who specializes in treating older adults)
You have tried generic amantadine immediate-release capsules, tablets or solution

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AMBRISENTAN

Generic	Brand				
AMBRISENTAN	LETAIRIS, AMBRISENTAN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Effective: 07/01/24

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AMIFAMPRIDINE

Generic	Brand			
AMIFAMPRIDINE	FIRDAPSE			
AMIFAMPRIDINE	RUZURGI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for approval:

A. You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
B. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or hematologist-oncologist (a type of blood-cancer doctor)
C. Your diagnosis is confirmed by ALL of the following:
    1. Electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing
    2. Three clinical symptoms of muscle weakness, autonomic dysfunction (nerve dysfunction), and decreased tendon reflexes
D. **If you are requesting Firdapse, approval also requires:**
    1. You are 6 years of age or older

RENEWAL CRITERIA

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
B. You have experienced improvement or stabilization in muscle weakness compared to baseline

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Effective: 07/01/24

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AMIKACIN LIPOSOMAL INHALATION

Generic	Brand				
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:
You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease
You are 18 years of age or older
You have limited or no alternative treatment options
You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
Arikayce will be used as part of a combination antibacterial drug regimen

RENEWAL CRITERIA

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:
You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease
You have NOT had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
You have experienced an improvement in symptoms

Effective: 04/01/26

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AMIVANTAMAB

Generic	Brand				
AMIVANTAMAB-VMJW	RYBREVANT				
AMIVANTAMAB-HYALURONIDASE-LPUJ	RYBREVANT FASPRO				

GUIDELINES FOR USE

Our guideline named **AMIVANTAMAB (Rybrevant, Rybrevant Faspro)** requires the following rule(s) be met for approval:

You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue, lymph nodes, or other parts of the body)

You are 18 years of age or older

If you have epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), approval also requires ONE of the following:

Your mutation is detected by a Food and Drug Administration (FDA)-approved test AND the requested medication will be used in combination with lazertinib (Lazcluze)

The requested medication will be used in combination with carboplatin and pemetrexed AND your disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (such as Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If you have epidermal growth factor receptor (EGFR: type of protein) exon 20 insertion mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, approval also requires you meet ONE of the following:

The requested medication will be used in combination with carboplatin and pemetrexed

The requested medication will be used as a single agent AND your disease has progressed on or after platinum-based chemotherapy (such as cisplatin, carboplatin)

Effective: 01/12/26

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AMLODIPINE

Generic	Brand				
AMLODIPINE BESYLATE	NORLIQVA				

GUIDELINES FOR USE

Our guideline named **AMLODIPINE (Norliqva)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Hypertension (high blood pressure)
- Chronic stable angina (a type of heart condition)
- Confirmed or suspected vasospastic angina (Prinzmetal's or variant angina) (a type of heart condition)
- Angiographically documented coronary artery disease (a type of heart condition that has been confirmed by a type of imaging test)

If you have hypertension, approval also requires:

- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have chronic stable angina, approval also requires:

- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have confirmed or suspected vasospastic angina (Prinzmetal's or variant angina), approval also requires:

- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have angiographically documented coronary artery disease (CAD), approval also requires:

- You do not have heart failure (a type of heart condition) OR an ejection fraction (evaluates heart function) of less than 40 percent
- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

Effective: 10/01/25

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ANABOLIC STEROIDS

Generic	Brand				
OXYMETHOLONE	ANADROL-50				
OXANDROLONE	OXANDRIN, OXANDROLONE				

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50

Our guideline named **ANABOLIC STEROIDS (Anadrol-50)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Anemia (lack of healthy red blood cells) caused by acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, hypoplastic anemias, or Fanconi's anemia
- Cachexia (severe weight and muscle loss) associated with AIDS (acquired immune deficiency syndrome: a type of immune system disorder caused by a virus infection)

You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

You do not have ANY of the following contraindications to (harmful for you to use) anabolic steroid therapy:
- Known or suspected prostate or breast cancer in male patients
- Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
- Known or suspected nephrosis (type of kidney disorder)
- Known or suspected hypercalcemia (high calcium levels)
- Severe hepatic (liver) dysfunction

(Initial criteria continued on next page)

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INITIAL CRITERIA - ANADROL-50 (CONTINUED)

If you have cachexia associated with AIDS, approval also requires:

- You are on anti-retroviral therapy (therapy that treats a type of viral infection)
- You have a viral load (amount of virus in your blood) of less than 200 copies per mL within the past 3 months
- Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist (SBS), or infectious disease specialist
- You meet ONE of the following:
  - You have 10% unintentional weight loss over 12 months
  - You have 7.5% unintentional weight loss over 6 months
  - You have 5% body cell mass (BCM) loss within 6 months
  - You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BMI of less than 18.5 kg per meter squared

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ANABOLIC STEROIDS

INITIAL CRITERIA (CONTINUED)

OXANDRIN

Our guideline named **ANABOLIC STEROIDS (Oxandrin, oxandrolone)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Weight loss
- Protein catabolism (breakdown) caused by long-term use of corticosteroids
- Bone pain accompanying osteoporosis (type of bone condition)
- Turner's syndrome (type of genetic disorder)
- Cachexia (severe weight and muscle loss) associated with AIDS (acquired immune deficiency syndrome: a type of immune system disorder caused by a virus infection)

You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

You do not have ANY of the following contraindications to (harmful for you to use) anabolic steroid therapy:
- Known or suspected prostate or breast cancer in male patients
- Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
- Known or suspected nephrosis (type of kidney disorder)
- Known or suspected hypercalcemia (high calcium levels)
- Severe hepatic (liver) dysfunction

If you have weight loss, approval also requires:
- Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
- The medication is being used as add-on therapy to help weight gain

If you have cachexia associated with AIDS, approval also requires:
- You are on anti-retroviral therapy (treatment for a type of viral infection)
- You have a viral load (amount of virus in the blood) of less than 200 copies per mL within the past 3 months
- Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist (SBS) or infectious disease specialist
- You meet ONE of the following:
  - You have 10% unintentional weight loss over 12 months
  - You have 7.5% unintentional weight loss over 6 months
  - You have 5% body cell mass (BCM) loss within 6 months
  - You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BMI of less than 18.5 kg per meter squared

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ANABOLIC STEROIDS

RENEWAL CRITERIA

NOTE: For the diagnoses of anemia, weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's syndrome, please refer to the Initial Criteria section.

OXANDRIN and ANADROL-50

Our guideline named **ANABOLIC STEROIDS (Oxandrin, oxandrolone, Anadrol-50)** requires the following rule(s) be met for renewal:

You have cachexia (severe weight and muscle loss) associated with AIDS (acquired immune deficiency syndrome: a type of immune system disorder caused by a virus infection)

You are on anti-retroviral therapy (treatment for a type of viral infection)

Your viral load (amount of virus in the blood) is less than 200 copies per mL within the past 3 months

You have had a 10% increase in weight from baseline (before treatment) (current weight must have been measured within the last 4 weeks)

You have not received more than 24 weeks of therapy in a calendar year

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Effective: 02/01/26

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ANAKINRA

Generic	Brand				
ANAKINRA	KINERET				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Cryopyrin-associated periodic syndromes (CAPS: a type of immune disorder) including neonatal-onset multisystem inflammatory disease (NOMID: a type of immune system disorder)
   3. Deficiency of interleukin-1 receptor antagonist (DIRA: a type of immune system disorder)
   4. Active Still's Disease/Adult-Onset Still's Disease (AOSD) (an autoinflammatory disease)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have cryopyrin-associated periodic syndromes, including neonatal-onset multisystem inflammatory disease, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
   2. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), skeletal (bone) abnormalities
   3. You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes, including Neonatal-Onset Multisystem Inflammatory Disease (types of immune system disorder)

(Initial criteria continued on next page)

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

D. **If you have deficiency of interleukin-1 receptor antagonist, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN gene* (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body])
   2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: nail shedding)
   3. You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (a type of immune system disorder)

F. **If you have Active Still's Disease/Adult-Onset Still's Disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   2. You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Active Still's Disease/Adult-Onset Still's Disease (an autoinflammatory disease)

E. NOTE: Kineret will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ANAKINRA

RENEWAL CRITERIA

NOTE: For the diagnoses of cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA), please refer to the Initial Criteria section.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Active Still's Disease/Adult-Onset Still's Disease (AOSD) (an autoinflammatory disease)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**

C. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   1. You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   2. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have Active Still's Disease/Adult-Onset Still's Disease, renewal also requires:**
   1. You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Active Still's Disease/Adult-Onset Still's Disease (an autoinflammatory disease)
   2. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis [a type of joint condition]) or you have achieved a reduction (decrease) in corticosteroid (such as prednisone) dose
   3. Your disease is still clinically active (remission [reduction or disappearance of the signs and symptoms of a disease] has not been attained) OR discontinuing therapy will be harmful for you

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ANIFROLUMAB-FNIA (NSA)

Generic	Brand				
ANIFROLUMAB-FNIA	SAPHNELO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ANIFROLUMAB-FNIA (Saphnelo)** requires the following rule(s) be met for approval:

A. You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
D. You are receiving standard SLE therapy (such as oral corticosteroids, antimalarials, or immunosuppressants)
E. You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus

RENEWAL CRITERIA

Our guideline named **ANIFROLUMAB-FNIA (Saphnelo)** requires the following rule(s) be met for renewal:

A. You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
B. You have shown clinical improvement while on Saphnelo
C. You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus

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ANIFROLUMAB-FNIA SQ

Generic	Brand				
ANIFROLUMAB-FNIA	SAPHNELO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ANIFROLUMAB-FNIA SQ (Saphnelo)** requires the following rule(s) be met for approval:

A. You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
D. You are currently using ONE clinical standard of care medication: oral corticosteroid (such as prednisone), antimalarial (such as hydroxychloroquine), non-steroidal anti-inflammatory drug (NSAID, such as ibuprofen), immunosuppressive agent (such as azathioprine, cyclosporine)
E. You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus (a type of immune condition)

RENEWAL CRITERIA

Our guideline named **ANIFROLUMAB-FNIA SQ (Saphnelo)** requires the following rule(s) be met for renewal:

A. You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
B. You have shown clinical improvement while on Saphnelo
C. You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus (a type of immune condition)

Effective: 08/01/26

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APALUTAMIDE

Generic	Brand				
APALUTAMIDE	ERLEADA				

GUIDELINES FOR USE

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
- Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)

You meet ONE of the following:
- You have received a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- Erleada will be used together with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Effective: 03/04/26

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APOMORPHINE - APOKYN

Generic	Brand				
APOMORPHINE HCL	APOKYN, APOMORPHINE HCL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for approval:
You have advanced Parkinson's disease (PD: a type of movement disorder)
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
The requested medication will be used for acute, intermittent treatment of hypomobility, 'OFF' episodes (period of symptoms in between doses) associated with advanced Parkinson's disease (a type of movement disorder)
You are experiencing at least 3 hours of 'off' time (period of symptoms in between doses) on your current Parkinson’s disease drug treatment (medication for a type of movement disorder)
You have shown a clear responsiveness to treatment with levodopa
You meet ONE of the following:
- You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
- You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

Your doctor has optimized your medication therapy as shown by ALL of the following:
- You had a change in levodopa/carbidopa dosing strategy or formulation
- You have tried or have a contraindication to (harmful for you to use) TWO Parkinson disease medications from two different classes: dopamine agonist (ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (entacapone, tolcapone), adenosine receptor antagonist A2A (Nourianz [istradefylline])

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APOMORPHINE - APOKYN

RENEWAL CRITERIA

Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for renewal:
You have advanced Parkinson's disease (PD: a type of movement disorder)
You have experienced improvement with motor fluctuations (changes in the ability to move) during 'OFF' episodes with the use of the requested medication (such as improvement in speech, facial expression, tremor [shaking] at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

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APOMORPHINE - ONAPGO

Generic	Brand				
APOMORPHINE HCL	ONAPGO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for approval:

A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. Onapgo will be used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. Your disease is responsive to treatment with levodopa
E. Your current medication regimen (treatment plan), including levodopa, has been at a stable dose for at least 28 days
F. Your motor symptoms are currently uncontrolled (defined as an average 'off' time of at least 3 hours per day, with a minimum of 2 hours each day)
G. You do not have any of the following: orthostatic hypotension (a type of low blood pressure), history of prolonged QTc (a type of irregular heart rhythm) (greater than 450 msec for male or greater than 470 msec for female), active or uncontrolled psychosis (a type of mental health disorder), active or uncontrolled depression (a type of mental health disorder)

RENEWAL CRITERIA

Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for renewal:
You have advanced Parkinson's disease (PD: a type of movement disorder)
You have experienced improvement in motor symptoms while on Onapgo

Effective: 03/10/25

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APREMILAST

Generic	Brand				
APREMILAST	OTEZLA, OTEZLA XR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **APREMILAST (Otezla, Otezla XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Plaque psoriasis (PsO: a type of skin condition)
   3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of psoriatic arthritis

C. **If you have mild plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) one clinical standard of care agent: a conventional (standard) systemic (treatment that targets the entire body) medication (such as methotrexate, acitretin, cyclosporine) OR a conventional topical medication (such as topical corticosteroids [such as betamethasone dipropionate, clobetasol propionate])
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of mild plaque psoriasis

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to the requested medication
   b. You have a static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) score of 2
   c. You have a Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) score of 2 to 9

D. **If you have moderate to severe plaque psoriasis, approval also requires:**
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of moderate to severe plaque psoriasis
4. You meet ONE of the following:
   a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor, or JAK (Janus kinase) inhibitor for the same indication
5. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to the requested medication
   b. You have psoriasis covering 3 percent or more of body surface area (BSA)
   c. You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

(Initial criteria continued on next page)

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APREMILAST

INITIAL CRITERIA (CONTINUED)

E. **If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE or more conservative clinical standard of care treatments (such as colchicine, topical corticosteroid [such as triamcinolone], oral corticosteroid [such as prednisolone])
   4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet’s disease

RENEWAL CRITERIA

Our guideline named **APREMILAST (Otezla, Otezla XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Plaque psoriasis (PsO: a type of skin condition)
   3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of psoriatic arthritis

(Renewal criteria continued on next page)

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APREMILAST

RENEWAL CRITERIA (CONTINUED)

C. **If you have mild plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more OR a decrease in static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) by at least a 2-point reduction from baseline
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of mild plaque psoriasis

D. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of moderate to severe plaque psoriasis

E. **If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:**
   1. You have achieved or maintained clinical benefit compared to baseline (such as an improvement in pain scores, number of ulcers)
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet's disease

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APREPITANT

Generic	Brand				
APREPITANT	EMEND				

GUIDELINES FOR USE

Our guideline named **APREPITANT (Emend)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Prevention of acute (short-term) and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin (cancer treatment that causes nausea and vomiting)
   2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) (cancer treatment that causes nausea and vomiting)

B. You have a contraindication to (harmful for you to use) or are unable to swallow aprepitant capsules

Effective: 07/01/26

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APROCITENTAN

Generic	Brand				
APROCITENTAN	TRYVIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for approval:

A. You have hypertension (high blood pressure)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)
D. Your blood pressure is NOT controlled on at least three anti-hypertensive medications (medications used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine]), with at least one being a diuretic (such as hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks
E. You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), or poor therapeutic adherence (not keeping up with therapy)
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medication: spironolactone, eplerenone

RENEWAL CRITERIA

Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for renewal:

A. You have hypertension (high blood pressure)
B. You continue to benefit from Tryvio

Effective: 07/01/26

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ARIMOCLOMOL

Generic	Brand				
ARIMOCLOMOL CITRATE	MIPLYFFA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for approval:

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)
D. Miplyffa will used in combination with miglustat (Zavesca)

RENEWAL CRITERIA

Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for renewal:

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You have shown improvement or a slowing of disease progression

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ASCIMINIB

Generic	Brand				
ASCIMINIB HYDROCHLORIDE	SCEMBLIX				

GUIDELINES FOR USE

Our guideline named **ASCIMINIB (Scemblix)** requires the following rule(s) be met for approval:
You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase (CP)
You are 18 years of age or older
You meet ONE of the following:
- Your cancer is newly diagnosed (such as you are starting or previously started Scemblix treatment at the time your condition was identified)
- Your cancer has the T315I mutation (abnormal change in a type of gene); you had a mutational analysis (a type of lab test) prior to the start of therapy; AND Scemblix is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on the profile for the breakpoint cluster region-Abelson murine leukemia 1 (BCR-ABL1: a type of gene) mutation
- You have been previously treated AND you had a mutational analysis prior to the start of therapy and Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on the profile for the BCR-ABL1 mutation

Effective: 08/11/25

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ASPARAGINASE ERWINIA-RYWN

Generic	Brand				
ASPARAGINASE ERWINIA-RYWN	RYLAZE				

GUIDELINES FOR USE

Our guideline named **ASPARAGINASE ERWINIA-RYWN (Rylaze)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acute lymphoblastic leukemia (ALL: a type of blood cancer)
- Lymphoblastic lymphoma (LBL: a type of immune system cancer)

You are 1 month of age or older
You have developed a hypersensitivity (allergic reaction) to E.coli-derived asparaginase (an enzyme/protein that is from a type of bacteria)
Rylaze will be used as a component of a multi-agent chemotherapeutic regimen (treatment using multiple drugs)

Effective: 02/01/26

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ASFOTASE ALFA

Generic	Brand				
ASFOTASE ALFA	STRENSIQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Perinatal/infantile-onset hypophosphatasia (HPP: a type of genetic condition)
- Juvenile-onset hypophosphatasia (HPP: a type of genetic condition)

If you have perinatal/infantile-onset hypophosphatasia, approval also requires:
- You were 6 months of age or younger at the onset of hypophosphatasia
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You will NOT use Strensiq with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
- Your serum (blood) calcium and phosphate levels are NOT below the normal range
- You do NOT have a treatable form of rickets (type of bone condition in children)
- You meet ONE of the following:
  - You are positive for a tissue non-specific alkaline phosphatase (TNSALP: a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing
  - You meet at least TWO of the following:
    - Your serum alkaline phosphatase (type of enzyme) level is below the normal range for your age
    - Your serum pyridoxal-5'-phosphate (PLP: type of lab test) level is elevated AND you have not received vitamin B6 supplementation in the previous week
    - Your urine phosphoethanolamine (PEA: type of lab) level is above the normal range for your age
    - You have radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (appearing dark/black on x-ray image) or sclerosis (hardening of an area)]

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

You have TWO or more of the following:
- Rachitic chest deformity (chest bones are not normal)
- Craniosynostosis (premature closure of skull bones)
- Delay in skeletal growth resulting in delay of motor development
- History of vitamin B6 dependent seizures
- Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
- History or presence of fracture after birth not due to injury or delayed fracture healing

If you have juvenile-onset hypophosphatasia, approval also requires:
- You were 18 years of age or younger at the onset of hypophosphatasia
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You will NOT use Strensiq with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
- Your serum (blood) calcium and phosphate levels are NOT below the normal range
- You do NOT have a treatable form of rickets (softening and weakening of bones in children, usually due to low vitamin D)
- You meet ONE of the following:
  - You are positive for a tissue non-specific alkaline phosphatase (TNSALP: a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing
  - You meet at least TWO of the following:
    - Your serum alkaline phosphatase (type of enzyme) level is below the normal range for your age
    - Your serum pyridoxal-5'-phosphate (PLP: type of lab test) level is elevated AND you have not received vitamin B6 supplementation in the previous week
    - Your urine phosphoethanolamine (PEA: type of lab test) level is above the normal range for your age
    - You have radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency (appearing dark/black on x-ray image) or sclerosis (hardening of an area)]
    - You have TWO or more of the following:
      - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
      - Premature loss of primary teeth prior to 5 years of age
      - Delay in skeletal growth leading to motor development delay
      - History or presence of fracture after birth not due to injury or delayed fracture healing

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ASFOTASE ALFA

RENEWAL CRITERIA

Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule(s) be met for renewal:

You have experienced an improvement in the skeletal characteristics (bones, teeth) of hypophosphatasia (HPP: type of genetic condition). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (appearing dark/black on x-ray image), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.

You will NOT use Strensiq with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])

Effective: 02/01/26

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ATEZOLIZUMAB

Generic	Brand				
ATEZOLIZUMAB	TECENTRIQ				

GUIDELINES FOR USE

Our guideline named **ATEZOLIZUMAB (Tecentriq)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-small cell lung cancer (NSCLC: a type of lung cancer)
   2. Metastatic non-squamous non-small cell lung cancer (NSq NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer)
   4. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
   5. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   6. Unresectable or metastatic alveolar soft part sarcoma (ASPS: a type of soft tissue cancer that cannot be removed by surgery or has spread to other parts of the body)
   7. Muscle invasive bladder cancer (MIBC: a type of bladder cancer that has spread to the muscle)

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GUIDELINES FOR USE (CONTINUED)

B. **If you have non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is stage II to IIIA; Tecentriq will be used as adjuvant (add-on) treatment following resection (removal of tissue or organ) and platinum-based chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin, oxaliplatin); AND your tumor(s) express programmed death-ligand 1 (PD-L1: type of protein) on at least 1% of tumor cells, as determined by a Food and Drug Administration (FDA)-authorized test
      b. Your cancer is metastatic (has spread to other parts of the body) and you meet ONE of the following:
         i. Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
         ii. Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have tumor(s) that have high programmed death-ligand 1 (PD-L1: type of protein) expression (PD-L1 stained at least 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering at least 10% of the tumor area), as determined by a Food and Drug Administration (FDA) authorized test
         iii. Your cancer has an anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
         iv. Your cancer has an epidermal growth factor receptor (EGFR: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

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GUIDELINES FOR USE (CONTINUED)

C. **If you have metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor abnormalities (type of abnormal gene)
   3. Tecentriq will be used in combination with bevacizumab, paclitaxel, and carboplatin OR in combination with paclitaxel protein-bound and carboplatin

D. **If you have extensive-stage small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Tecentriq will be used in combination with carboplatin and etoposide
      b. Tecentriq will be used in combination with Zepzelca (lurbinectedin) AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide

E. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. You have NOT previously been treated with systemic therapy (treatment that targets the entire body)
   2. Tecentriq will be used in combination with bevacizumab

F. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. Tecentriq will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
   2. Your cancer is BRAF V600 mutation (abnormal change in a type of gene)-positive

G. **If you have unresectable or metastatic alveolar soft part sarcoma, approval also requires:**
   1. You are 2 years of age or older

H. **If you have muscle invasive bladder cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Tecentriq will be used as adjuvant (add-on) treatment after a cystectomy (bladder removal surgery)
   3. You have circulating tumor DNA molecular residual disease (ctDNA MRD: traces of cancer DNA in your body), as determined by a Food and Drug Administration (FDA)-authorized test

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ATEZOLIZUMAB-HYALURONIDASE-TQJS

Generic	Brand				
ATEZOLIZUMAB-HYALURONIDASE-TQJS	TECENTRIQ HYBREZA				

GUIDELINES FOR USE

Our guideline named **ATEZOLIZUMAB-HYALURONIDASE-TQJS (Tecentriq Hybreza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-small cell lung cancer (NSCLC: a type of lung cancer)
   2. Metastatic non-squamous non-small cell lung cancer (NSq NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer)
   4. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   5. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   6. Unresectable or metastatic alveolar soft part sarcoma (ASPS: a type of soft tissue cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   7. Muscle invasive bladder cancer (MIBC: a type of bladder cancer that has spread to the muscle)

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GUIDELINES FOR USE (CONTINUED)

B. **If you have non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is Stage II to IIIA; Tecentriq Hybreza will be used as adjuvant treatment (additional treatment) following resection (removal of tissue or organ) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin); AND your tumor(s) express programmed death-ligand 1 (PD-L1: type of protein) on at least 1% of tumor cells, as determined by a Food and Drug Administration (FDA)-authorized test
      b. Your cancer is metastatic (has spread to other parts of the body) and you meet ONE of the following:
         i. Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have experienced disease progression (worsening) during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
         ii. Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have tumors that have high programmed death-ligand 1 (PD-L1: type of protein) expression (PD-L1 stained at least 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering at least 10% of the tumor area), as determined by a Food and Drug Administration (FDA)- authorized test
         iii. Your cancer has an anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene), and your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
         iv. Your cancer has an epidermal growth factor receptor (EGFR: a type of protein) mutation (abnormal change in a type of gene), and your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

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GUIDELINES FOR USE (CONTINUED)

C. **If you have metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor abnormalities (type of abnormal gene)
   3. Tecentriq Hybreza will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin

D. **If you have extensive-stage small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Tecentriq Hybreza will be used in combination with carboplatin and etoposide
      b. Tecentriq Hybreza will be used in combination with Zepzelca (lurbinectedin) AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq Hybreza or intravenous (injection into the vein) Tecentriq (atezolizumab), carboplatin, and etoposide

E. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have NOT previously been treated with systemic therapy (treatment that targets the entire body)
   3. Tecentriq Hybreza will be used in combination with bevacizumab

F. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You are 18 years of age or older
   2. Tecentriq Hybreza will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
   3. Your cancer is BRAF V600 mutation (abnormal change in a type of gene)-positive, as determined by a Food and Drug Administration (FDA)-approved test

G. **If you have unresectable or metastatic alveolar soft part sarcoma, approval also requires:**
   1. You are 18 years of age or older

H. **If you have muscle invasive bladder cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Tecentriq Hybreza will be used as adjuvant (add-on) treatment after a cystectomy (bladder removal surgery)
   3. You have circulating tumor DNA molecular residual disease (ctDNA MRD: traces of cancer DNA in your body), as determined by a Food and Drug Administration (FDA)-authorized test

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ATOGEPANT

Generic	Brand				
ATOGEPANT	QULIPTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Episodic migraines (a type of headache)
- Chronic migraines (a type of headache)

If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine (a type of headache) prevention

If you have chronic migraines (15 or more headache days per month), approval also requires:
- You are 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine (a type of headache) prevention

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ATOGEPANT

RENEWAL CRITERIA

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
The request is for the preventive treatment of migraines (a type of headache)
You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine (a type of headache) prevention
You meet ONE of the following:
- You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Qulipta therapy
- You have experienced a decrease in migraine (a type of headache) severity with Qulipta therapy
- You have experienced a decrease in migraine (a type of headache) duration with Qulipta therapy

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Effective: 04/01/26

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ATORVASTATIN

Generic	Brand				
ATORVASTATIN CALCIUM	ATORVALIQ				

GUIDELINES FOR USE

Our guideline named **ATORVASTATIN (Atorvaliq)** requires the following rule(s) be met for approval:

You have a contraindication to (harmful for you to use) or are unable to swallow atorvastatin oral tablets

Requests for zero-dollar cost share also requires the following:

You are between 40 to 75 years old

The requested quantity is within the low to moderate intensity daily dosage of 10mg to 20mg

You are NOT concurrently (at the same time) taking any of the following secondary prevention medications for cardiovascular disease (heart disease):

Aspirin/dipyridamole (Aggrenox)
Clopidogrel (Plavix)
Dipyridamole
Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
Prasugrel (Effient)
Ticagrelor (Brilinta)
Ticlopidine
Vorapaxar (Zontivity)

Effective: 01/01/26

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ATRASENTAN

Generic	Brand				
ATRASENTAN HYDROCHLORIDE	VANRAFIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ATRASENTAN (Vanrafia)** requires the following rule(s) be met for approval:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You are 18 years of age or older
You are at risk of rapid disease progression (such as a urine protein-to-creatinine ratio [UPCR: a test that measures the amount of protein in urine] of at least 1.5 g/g)
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

RENEWAL CRITERIA

Our guideline named **ATRASENTAN (Vanrafia)** requires the following rule(s) be met for renewal:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You meet ONE of the following:
- You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
- You have improved or stable kidney function compared to baseline (before starting Vanrafia)

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AVACINCAPTAD PEGOL

Generic	Brand				
AVACINCAPTAD PEGOL SODIUM/PF	IZERVAY				

GUIDELINES FOR USE

Our guideline named **AVACINCAPTAD PEGOL (Izervay)** requires the following rule(s) be met for approval:

You have geographic atrophy (GA: an advanced type of eye disease) due to age-related macular degeneration (AMD: a type of eye disease)

Effective: 02/01/26

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AVACOPAN

Generic	Brand				
AVACOPAN	TAVNEOS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for approval:
You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]: conditions that affect the blood vessels)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
You are ANCA seropositive for anti-PR3 or anti-MPO (a type of lab test)
Tavneos will be used as adjunctive (add-on) therapy in combination with standard therapy including glucocorticoids (such as methylprednisolone, prednisone)

RENEWAL CRITERIA

Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for renewal:
You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]: conditions that affect the blood vessels)
You continue to benefit from the medication (such as improvement of clinical symptoms, if renal vasculitis [inflammation of blood vessels in the kidneys] - improvement in estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] and proteinuria [increased levels of protein in the urine] values, reduction of corticosteroid [a type of drug used to treat inflammation] dose without disease flares)

Effective: 02/01/26

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AVALGLUCOSIDASE ALFA-NGPT

Generic	Brand				
AVALGLUCOSIDASE ALFA-NGPT	NEXVIAZYME				

GUIDELINES FOR USE

Our guideline named **AVALGLUCOSIDASE ALFA-NGPT (Nexviazyme)** requires the following rule(s) be met for approval:
You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)
You are 1 year of age or older

Effective: 05/13/26

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AVAPRITINIB

Generic	Brand				
AVAPRITINIB	AYVAKIT				

GUIDELINES FOR USE

Our guideline named **AVAPRITINIB (Ayvakit)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Unresectable or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that cannot be removed through surgery or has spread to other parts of the body)
- Advanced systemic mastocytosis (AdvSM: a type of blood disorder), including aggressive systemic mastocytosis (ASM: a type of blood disorder), systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood disorder), or mast cell leukemia (MCL: a type of blood cancer)
- Indolent systemic mastocytosis (ISM: a type of blood disorder)

If you have unresectable or metastatic gastrointestinal stromal tumor, approval also requires:
- You are 18 years of age or older
- You have a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations (abnormal change in a type of gene)

If you have advanced systemic mastocytosis, approval also requires:
- You are 18 years of age or older

If you have indolent systemic mastocytosis, approval also requires:
- You are 18 years of age or older

Effective: 02/01/26

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AVATROMBOPAG

Generic	Brand				
AVATROMBOPAG MALEATE	DOPTELET, DOPTELET SPRINKLE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AVATROMBOPAG (Doptelet, Doptelet Sprinkle)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Thrombocytopenia (a type of blood disorder) in chronic (long-term) liver disease
   2. Persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)

B. **If you have thrombocytopenia in chronic liver disease, approval also requires:**
   1. You are 18 years of age or older
   2. You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   3. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L
   4. You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag])

C. **If you have persistent or chronic immune thrombocytopenia, approval also requires:**
   1. You are 1 year of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
   3. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L, OR you have a platelet (a type of blood cell) count of less than 50 x 10^9/L and had a prior bleeding event
   4. You will NOT use the requested medication concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

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AVATROMBOPAG

RENEWAL CRITERIA

NOTE: For the diagnosis of thrombocytopenia in chronic liver disease, please refer to the Initial Criteria section.

Our guideline named **AVATROMBOPAG (Doptelet, Doptelet Sprinkle)** requires the following rule(s) be met for renewal:

A. You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Doptelet) OR a decrease in bleeding events
C. You will NOT use the requested medication concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

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AVELUMAB

Generic	Brand				
AVELUMAB	BAVENCIO				

GUIDELINES FOR USE

Our guideline named **AVELUMAB (Bavencio)** requires the following rules be met for approval:
You have ONE of the following:
- Metastatic Merkel cell carcinoma (MCC: a type of skin cancer)
- Locally advanced or metastatic (disease that has spread) urothelial carcinoma (UC: type of urinary system cancer)
- Advanced renal cell carcinoma (RCC: a type of kidney cancer)

If you have metastatic Merkel Cell Carcinoma, approval also requires:
- You are 12 years of age or older

If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:
- Your disease has worsened during or after platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- Your disease has worsened within 12 months of neoadjuvant (treatment given before a main treatment) or adjuvant treatment (add-on to a main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- Your disease has not worsened with first-line platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin), AND Bavencio will be used as first-line maintenance treatment

If you have advanced renal cell carcinoma, approval also requires:
- Bavencio will be used in combination with Inlyta (axitinib)

Effective: 02/01/26

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AVUTOMETINIB-DEFACTINIB

Generic	Brand				
AVUTOMETINIB-DEFACTINIB	AVMAPKI-FAKZYNJA				

GUIDELINES FOR USE

Our guideline named **AVUTOMETINIB-DEFACTINIB (Avmapki-Fakzynja)** requires the following rule(s) be met for approval:

You have recurrent low-grade serous ovarian cancer (LGSOC: a type of reproductive system cancer that has returned)

You are 18 years of age or older

Your cancer has a KRAS mutation (a type of abnormal gene)

You have received prior systemic therapy (such as platinum-based chemotherapy [a type of therapy to treat cancer])

Effective: 06/01/25

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AXATILIMAB-CSFR

Generic	Brand				
AXATILIMAB-CSFR	NIKTIMVO				

GUIDELINES FOR USE

Our guideline named **AXATILIMAB-CSFR (Niktimvo)** requires the following rule(s) be met for approval:

a. You have chronic graft-versus-host disease (cGVHD: a type of long-term immune disorder)
b. You weigh at least 40 kilograms (88 pounds)
c. You have failed at least TWO lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
d. You will NOT use Niktimvo concurrently (at the same time) with Jakafi (ruxolitinib), Rezurock (belumosudil), or Imbruvica (ibrutinib)

Effective: 06/01/25

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AXITINIB

Generic	Brand				
AXITINIB	INLYTA				

GUIDELINES FOR USE

Our guideline named **AXITINIB (Inlyta)** requires the following rule(s) be met for approval:
You have advanced renal cell carcinoma (RCC: a type of kidney cancer)
You meet ONE of the following:
- Inlyta will be used in combination with avelumab (Bavencio)
- Inlyta will be used in combination with pembrolizumab (Keytruda)
- You have tried at least one systemic therapy (treatment that targets the entire body) for renal cell carcinoma (such as Nexavar [sorafenib], Torisel [temsirolimus], Sutent [sunitinib], Votrient [pazopanib], Avastin [bevacizumab] in combination with interferon)

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AZACITIDINE

Generic	Brand				
AZACITIDINE	ONUREG				

GUIDELINES FOR USE

Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:
You have acute myeloid leukemia (AML: type of blood and bone marrow cancer)
You are 18 years of age or older
You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
You are NOT able to complete intensive curative therapy (treatment to cure the disease)

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AZELAIC ACID

Generic	Brand				
AZELAIC ACID	AZELEX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AZELAIC ACID (Azelex)** requires the following rule(s) be met for approval:

A. You have acne vulgaris (a type of skin condition)
B. Azelex will NOT be used concurrently (at the same time) with other acne therapies that are only available as brand name (such as Aklief, Cabtreo, Winlevi)
C. You have tried or have a contraindication to (harmful for you to use) THREE preferred generic topical medications for the treatment of acne (such as azelaic acid 15% gel, benzoyl peroxide, topical clindamycin)

RENEWAL CRITERIA

Our guideline named **AZELAIC ACID (Azelex)** requires the following rule(s) be met for renewal:

A. You have acne vulgaris (a type of skin condition)
B. Azelex will NOT be used concurrently (at the same time) with other acne therapies that are only available as brand name (such as Aklief, Cabtreo, Winlevi)

Effective: 07/01/26

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AZTREONAM INHALED

Generic	Brand				
AZTREONAM LYSINE	CAYSTON				

GUIDELINES FOR USE

Our guideline named **AZTREONAM INHALED (Cayston)** requires the following rule(s) be met for approval:
You have cystic fibrosis (CF: a type of lung disorder)
You are 7 years of age or older
You have a lung infection with a Gram-negative bacterial species (a type of bacteria such as *Pseudomonas aeruginosa*)

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BACLOFEN

Generic	Brand				
BACLOFEN	OZOBAX, OZOBAX DS, BACLOFEN				
BACLOFEN	FLEQSUVY, BACLOFEN				

GUIDELINES FOR USE

Our guideline named **BACLOFEN (Ozobax, Ozobax DS, Fleqsuvy)** requires the following rule(s) be met for approval:

A. You have a contraindication to (harmful for you to use) or are unable to swallow baclofen oral tablets

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BARICITINIB

Generic	Brand				
BARICITINIB	OLUMIANT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Severe alopecia areata (a type of hair loss)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

(Initial criteria continued on next page)

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BARICITINIB

INITIAL CRITERIA (CONTINUED)

C. **If you have severe alopecia areata, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have had at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool), for more than 6 months
   4. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)

D. NOTE: Olumiant will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Severe alopecia areata (a type of hair loss)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. **If you have severe alopecia areata, renewal also requires:**
   1. You have experienced improvement while on therapy (such as scalp hair coverage)
   2. You will NOT use Olumiant concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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BAXDROSTAT

Generic	Brand				
BAXDROSTAT	BAXFENDY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BAXDROSTAT (Baxfendy)** requires the following rule(s) be met for approval:

A. You have hypertension (high blood pressure)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)
D. Your blood pressure is NOT controlled on at least three anti-hypertensive medications (medications used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine]), with at least one being a diuretic (such as hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks
E. You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (except primary aldosteronism [a type of hormone disorder] and sleep apnea [a type of sleep condition with difficulty breathing])
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: spironolactone, eplerenone

RENEWAL CRITERIA

Our guideline named **BAXDROSTAT (Baxfendy)** requires the following rule(s) be met for renewal:

A. You have hypertension (high blood pressure)
B. You have had blood pressure reduction (decrease) or achieved blood pressure goal

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BEDAQUILINE

Generic	Brand				
BEDAQUILINE FUMARATE	SIRTURO				

GUIDELINES FOR USE

Our guideline named **BEDAQUILINE (Sirturo)** requires the following rule(s) be met for approval:
You have pulmonary tuberculosis (TB: a type of lung infection)
You meet ONE of the following:
- You have an isolate of *Mycobacterium tuberculosis* (a type of bacterium) that is resistant to rifampin and isoniazid; you are 2 years of age or older; and you will use Sirturo in combination with at least 3 other antibiotics
- You have an isolate of *Mycobacterium tuberculosis* that is resistant to rifampin and isoniazid; you are 18 years of age or older; and you will use Sirturo in combination with pretomanid and linezolid
- You have an isolate of *Mycobacterium tuberculosis* that is resistant to isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside antibiotic; you are 18 years of age or older; and you will use Sirturo in combination with pretomanid and linezolid

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BELANTAMAB MAFODOTIN-BLMF

Generic	Brand				
BELANTAMAB MAFODOTIN-BLMF	BLENREP				

GUIDELINES FOR USE

Our guideline named **BELANTAMAB MAFODOTIN-BLMF (Blenrep)** requires the following rule(s) be met for approval:

You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)

You are 18 years of age or older

Blenrep will be used in combination with bortezomib and dexamethasone

You have received at least two prior lines of therapy, including a proteasome inhibitor (such as Ninlaro [ixazomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide])

Effective: 12/01/25

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BELIMUMAB

Generic	Brand				
BELIMUMAB	BENLYSTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Systemic lupus erythematosus (SLE: a type of immune condition)
   2. Lupus nephritis (LN: a type of immune condition that affects the kidneys)

B. **If you have systemic lupus erythematosus, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using corticosteroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (standard therapy for the treatment of systemic lupus erythematosus [SLE])
   4. You will NOT use Benlysta concurrently (at the same time) with another systemic biologic (such as Sahnelo [anifrolumab-fnia]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of SLE

C. **If you have lupus nephritis, approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
   3. You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs [NSAIDs], or immunosuppressives
   4. You will NOT use Benlysta concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of lupus nephritis

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BELIMUMAB

RENEWAL CRITERIA

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Systemic lupus erythematosus (SLE: a type of immune condition)
   2. Lupus nephritis (LN: a type of immune condition that affects the kidneys)

B. **If you have systemic lupus erythematosus, renewal also requires:**
   1. You have shown clinical improvement while on Benlysta
   2. You will NOT use Benlysta concurrently (at the same time) with another systemic biologic (such as Sahnelo [anifrolumab-fnia]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus

C. **If you have lupus nephritis, renewal also requires:**
   1. You have shown clinical improvement in renal (kidney) response as compared to baseline (before starting Benlysta) laboratory values (estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] or proteinuria [level of protein in the urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)
   2. You will NOT use Benlysta concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of lupus nephritis

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Effective: 01/01/25

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BELINOSTAT (NSA)

Generic	Brand			
BELINOSTAT	BELEODAQ			

GUIDELINES FOR USE

Our guideline named **BELINOSTAT (Beleodaq)** requires that the following rule be met for approval:
You have a diagnosis of relapsed or refractory (your condition has gotten worse after improving) peripheral T-cell lymphoma (PTCL; cancer that affects a type of immune system cells)
You are 18 years of age or older

Effective: 07/01/20

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BELUMOSUDIL

Generic	Brand				
BELUMOSUDIL MESYLATE	REZUROCK				

GUIDELINES FOR USE

Our guideline named **BELUMOSUDIL (Rezurock)** requires the following rule(s) be met for approval:

A. You have chronic graft-versus-host-disease (cGVHD: a type of long-term immune disorder)
B. You are 12 years of age or older
C. You have failed at least TWO lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
D. You will NOT use Rezurock concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

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BELZUTIFAN

Generic	Brand				
BELZUTIFAN	WELIREG				

GUIDELINES FOR USE

Our guideline named **BELZUTIFAN (Welireg)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Von Hippel-Lindau (VHL) disease (a genetic disorder that causes tumors to grow in the body)
   2. Renal cell carcinoma (RCC: a type of kidney cancer)
   3. pheochromocytoma (a type of rare tumor) or paraganglioma (a type of nerve condition)

B. **If you have von Hippel-Lindau disease, approval also requires:**
   1. You are 18 years of age or older
   2. You require therapy for associated renal cell carcinoma (RCC: a type of kidney cancer), central nervous system (CNS) hemangioblastomas (tumor in the brain or spinal cord), or pancreatic neuroendocrine tumors (pNET: tumor in the pancreas)
   3. You do NOT require immediate surgery

C. **If you have renal cell carcinoma, approval also requires ONE of the following:**
   1. You are 18 years of age or older; AND Welireg will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph); AND Welireg will be used for adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer); AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
   2. You are 18 years of age or older; AND your cancer is advanced; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer); AND you were previously treated with a programmed death receptor-1 (PD-1) inhibitor (such as Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (such as Bavencio [avelumab]); AND you were previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) (such as Nexavar [sorafenib])

D. **If you have pheochromocytoma or paraganglioma, approval also requires:**
   1. You are 12 years of age or older
   2. Your tumor is locally advanced (spread from where it started to nearby tissue or lymph nodes), unresectable (cannot be removed by surgery), or metastatic (has spread to other parts of the body)

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BENRALIZUMAB

Generic	Brand				
BENRALIZUMAB	FASENRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
   3. Hypereosinophilic syndrome (HES: a type of blood disorder)

B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
   4. Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as formoterol, salmeterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline, or an oral corticosteroid [such as prednisone])
   5. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. **If you have eosinophilic granulomatosis with polyangiitis, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels)

D. **If you have hypereosinophilic syndrome, approval also requires:**
   1. You are 12 years of age or older
   2. You have hypereosinophilic syndrome (HES: a type of blood disorder) without an identifiable non-hematologic (not present in the blood) secondary cause (HES is not caused by another condition)
   3. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   4. You have a blood eosinophil count (a type of lab test) of at least 1000 cells/mcL at the start of therapy
   5. You have a negative FIP1L1-PDFRA test (a type of lab test that detects a type of gene mutation)
   6. You have been stable on hypereosinophilic syndrome (HES: a type of blood disorder) therapy (corticosteroid [such as prednisone]) for at least 4 weeks
   7. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

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RENEWAL CRITERIA

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
   3. Hypereosinophilic syndrome (HES: a type of blood disorder)

B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Fasenra)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. Your percent predicted FEV1 (a type of lung test) has increased from pre-treatment baseline (before starting Fasenra)
      d. You have experienced a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:**
   1. You have a reduction in eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels) symptoms compared to baseline (before starting Fasenra), OR you have been able to decrease or eliminate (stop) corticosteroid (such as prednisone) use
   2. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of EGPA (a type of immune system disorder with inflammation of blood vessels)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have hypereosinophilic syndrome, renewal also requires:**
   1. You have a reduction in frequency/severity of hypereosinophilic syndrome (HES: a type of blood disorder) flares
   2. You have improved symptoms or reduced oral steroid (such as prednisone) requirements
   3. You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

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BERDAZIMER

Generic	Brand				
BERDAZIMER SODIUM	ZELSUVMI				

GUIDELINES FOR USE

Our guideline named **BERDAZIMER (Zelsuvmi)** requires the following rule(s) be met for approval:

A. You have molluscum contagiosum (MC: a viral skin infection)
B. You are 1 year of age or older
C. You will NOT use Zelsuvmi concurrently (at the same time) with another topical medication for the treatment of molluscum contagiosum (a viral skin infection) (such as Ycanth [cantharidin], Condylox [podofilox])
D. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: podofilox 0.5% topical solution

Effective: 05/20/26

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BEROTRALSTAT

Generic	Brand				
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 2 years of age or older
C. Orladeyo will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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BEROTRALSTAT

RENEWAL CRITERIA

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

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BETAINE

Generic	Brand				
BETAINE	CYSTADANE, BETAINE ANHYDROUS				

GUIDELINES FOR USE

Our guideline named **BETAINE (Cystadane)** requires the following rule(s) be met for approval:
You have homocystinuria (a type of genetic metabolic disorder), including cystathionine beta-synthase (CBS: a type of enzyme) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR: a type of enzyme) deficiency, cobalamin cofactor metabolism (cbl: vitamin B12 that is required for enzyme activity) defect

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BEVACIUMAB-ADCD (NSA)

Generic	Brand				
BEVACIZUMAB-ADCD	VEGZELMA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEVACIZUMAB-ADCD (Vegzelma)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Stage III or IV epithelial ovarian, fallopian tube (female sex organs), or primary peritoneal (abdomen) cancer
   8. Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs), or primary peritoneal (abdomen) cancer
   9. Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs), or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires ONE of the following:**
   1. Vegzelma will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
   2. Your disease has progressed (gotten worse) on a first-line bevacizumab-containing regimen AND Vegzelma will be used in combination with fluoropyrimidine- irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy as a second-line treatment
   3. Vegzelma will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

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BEVACIZUMAB-ADCD (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. Vegzelma will be used in combination with carboplatin and paclitaxel for first-line treatment

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. Vegzelma will be used in combination with interferon-alfa

F. **If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
   2. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VGEF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

G. **If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:**
   1. Vegzelma will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

H. **If you have Stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Vegzelma will be used following initial surgical resection (removal)
   2. Vegzelma will be used in combination with carboplatin and paclitaxel OR as a single agent after previous use in combination with carboplatin and paclitaxel

I. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Vegzelma will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
   2. You have received no more than two prior chemotherapy regimens

J. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires ONE of the following:**
   1. Vegzelma will be used in combination with carboplatin and paclitaxel OR with carboplatin and gemcitabine
   2. Vegzelma will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

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BEVACIZUMAB-ADCD (NSA)

INITIAL CRITERIA (CONTINUED)

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. Vegzelma will be used in combination with Tecentriq (atezolizumab)
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Our guideline named **BEVACIZUMAB-ADCD (Vegzelma)** requires the following rule(s) be met for renewal:

A. You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
B. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
C. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

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BEVACIZUMAB (NSA)

Generic	Brand				
BEVACIZUMAB	AVASTIN, BEVACIZUMAB				

GUIDELINES FOR USE

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   8. Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   9. Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You meet ONE of the following:
      a. Avastin will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
      b. Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Avastin will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy as a second-line treatment
      c. Avastin will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

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INITIAL CRITERIA (CONTINUED)

2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. Avastin will be used in combination with carboplatin and paclitaxel for first-line treatment
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. Avastin will be used in combination with interferon-alfa
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

F. **If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
   2. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

G. **If you have persistent, recurrent, or metastatic cervical cancer**, **approval also requires:**
   1. Avastin will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

H. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Avastin will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
   2. You have received no more than two prior chemotherapy regimens
   3. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

I. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. You meet ONE of the following:
      a. Avastin will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
      b. Avastin will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

J. **If you have stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Avastin will be used following initial surgical resection (removal)
   2. Avastin will be used in combination with carboplatin and paclitaxel OR as a single agent after previous use in combination with carboplatin and paclitaxel
   3. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. Avastin will be used in combination with Tecentriq (atezolizumab)
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)
   3. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for renewal:

A. You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
B. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
C. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

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BEVACIZUMAB-AWWB (NSA)

Generic	Brand				
BEVACIZUMAB-AWWB	MVASI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEVACIZUMAB-AWWB (Mvasi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   8. Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   9. Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires ONE of the following:**
   1. Mvasi will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
   2. Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Mvasi will be used in combination with fluoropyrimidine-irinotecan (such as FOLFIRI) or fluoropyrimidine-oxaliplatin (such as FOLFOX, CAPeOX) based chemotherapy as a second-line treatment
   3. Mvasi will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

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BEVACIZUMAB-AWWB (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. Mvasi will be used in combination with carboplatin and paclitaxel for first-line treatment

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. Mvasi will be used in combination with interferon-alfa

F. **If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
   2. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

G. **If you have persistent, recurrent, or metastatic cervical cancer**, **approval also requires:**
   1. Mvasi will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

H. **If you have Stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. Mvasi will be used following initial surgical resection (removal)
   2. Mvasi will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

I. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. Mvasi will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
   2. You have received no more than two prior chemotherapy regimens

J. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires ONE of the following:**
   1. Mvasi will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
   2. Mvasi will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

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BEVACIZUMAB-AWWB (NSA)

INITIAL CRITERIA (CONTINUED)

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. Mvasi will be used in combination with Tecentriq (atezolizumab)
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)

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BEVACIZUMAB-AWWB (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Our guideline named **BEVACIZUMAB-AWWB (Mvasi)** requires the following rule(s) be met for renewal:

A. You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
B. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
C. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

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BEVACIZUMAB-BVZR (NSA)

Generic	Brand			
BEVACIZUMAB-BVZR	ZIRABEV			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEVACIZUMAB-BVZR (Zirabev)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   8. Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   9. Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires ONE of the following:**
   1. Zirabev will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
   2. Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Zirabev will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CAPeOX) based chemotherapy as a second-line treatment
   3. Zirabev will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

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BEVACIZUMAB-BVZR (NSA)

INITIAL CRITERIA (CONTINUED)

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. Zirabev will be used in combination with carboplatin and paclitaxel for first-line treatment

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. Zirabev will be used in combination with interferon-alfa

F. **If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
   2. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

G. **If you have persistent, recurrent, or metastatic cervical cancer**, **approval also requires:**
   1. Zirabev will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

H. **If you have Stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Zirabev will be used following initial surgical resection (removal)
   2. Zirabev will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

I. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Zirabev will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
   2. You have received no more than two prior chemotherapy regimens

J. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires ONE of the following:**
   1. Zirabev will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
   2. Zirabev will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

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BEVACIZUMAB-BVZR (NSA)

INITIAL CRITERIA (CONTINUED)

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. Zirabev will be used in combination with Tecentriq (atezolizumab)
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Our guideline named **BEVACIZUMAB-BVZR (Zirabev)** requires the following rule(s) be met for renewal:

A. You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
B. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
C. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

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BEVACIUMAB-MALY (NSA)

Generic	Brand				
BEVACIZUMAB-MALY	ALYMSYS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEVACIZUMAB-MALY (Alymsys)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   8. Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   9. Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

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INITIAL CRITERIA (CONTINUED)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You meet ONE of the following:
      a. Alymsys will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
      b. Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Alymsys will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy as a second-line treatment
      c. Alymsys will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
   1. Alymsys will be used in combination with carboplatin and paclitaxel for first-line treatment
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

D. **If you have recurrent glioblastoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   1. Alymsys will be used in combination with interferon-alfa
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB-AWWB (NSA)

INITIAL CRITERIA (CONTINUED)

F. **If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
   2. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

G. **If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:**
   1. Alymsys will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

H. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Alymsys will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
   2. You have received no more than two prior chemotherapy regimens
   3. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

I. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. You meet ONE of the following:
      a. Alymsys will be used in combination with carboplatin and paclitaxel OR with carboplatin and gemcitabine
      b. Alymsys will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above
   2. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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INITIAL CRITERIA (CONTINUED)

J. **If you have stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
   1. Alymsys will be used following initial surgical resection (removal)
   2. Alymsys will be used in combination with carboplatin and paclitaxel OR as a single agent after previous use in combination with carboplatin and paclitaxel
   3. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. Alymsys will be used in combination with Tecentriq (atezolizumab)
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)
   3. You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB-MALY (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Our guideline named **BEVACIZUMAB-MALY (Alymsys)** requires the following rule(s) be met for renewal:

A. You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
B. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
C. You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

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BEVACIZUMAB-NWGD

Generic	Brand				
BEVACIZUMAB-NWGD	JOBEVNE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEVACIZUMAB-NWGD (Jobevne)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:

- Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain tumor)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread in the body)
- An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)
- Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

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BEVACIZUMAB-NWGD

INITIAL CRITERIA (CONTINUED)

If you have metastatic colorectal cancer, approval also requires:
- You meet ONE of the following:
  - Jobevne will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
  - Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Jobevne will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy
  - Jobevne will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Jobevne will be used in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have metastatic renal cell carcinoma, approval also requires:
- Jobevne will be used in combination with interferon-alfa
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB-NWGD

INITIAL CRITERIA (CONTINUED)

If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
- You will NOT Jobevne concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic (eye) indication

If you have persistent, recurrent, or metastatic cervical cancer, **approval also requires:**
- Jobevne will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
- You meet ONE of the following:
  - Your cancer is platinum-resistant recurrent (no longer responds to a type of treatment); Jobevne will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan; AND you have received no more than 2 prior chemotherapy regimens (received no more than 2 prior chemotherapy regimens)
  - Your cancer is platinum-sensitive recurrent (responds to a type of treatment); AND Jobevne will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single agent after previous use in combination with one of these carboplatin-containing chemotherapy regimens
  - Your cancer is stage III or IV; Jobevne will be used following initial surgical resection (removal); AND Jobevne will be used in combination with carboplatin and paclitaxel, or as a single agent after previous use in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB-NWGD

INITIAL CRITERIA (CONTINUED)

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
Jobevne will be used in combination with Tecentriq (atezolizumab)
You have not received prior systemic therapy (treatment that spreads throughout the body)
You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Our guideline named **BEVACIZUMAB-NWGD (Jobevne)** requires the following rule(s) be met for renewal:
You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT Jobevne concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

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Effective: 09/08/25

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BEXAROTENE

Generic	Brand				
BEXAROTENE	TARGRETIN, BEXAROTENE				

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

TARGRETIN (BEXAROTENE) CAPSULE

Our guideline named **BEXAROTENE (Targretin capsule)** requires the following rule(s) be met for approval:
You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer)
You are refractory (condition does not respond to treatment) to at least one prior systemic therapy (treatment that targets the entire body, such as gemcitabine, methotrexate, liposomal doxorubicin, bortezomib)

TARGRETIN (BEXAROTENE) GEL

Our guideline named **BEXAROTENE (Targretin gel)** requires the following rule(s) to be met for approval:
You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer) (Stage IA or IB)
You meet ONE of the following:
- You have refractory (condition does not respond) or persistent (condition continues to exist) disease after other therapies
- You have not tolerated other therapies

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BIMEKIZUMAB-BKZX

Generic	Brand				
BIMEKIZUMAB-BKZX	BIMZELX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You are a candidate for systemic therapy (treatment that targets the entire body) or phototherapy (light therapy)
   4. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   5. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Bimzelx
   b. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA)
   c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

C. **If you have psoriatic arthritis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
5. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Bimzelx
   b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
   c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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INITIAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

F. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

RENEWAL CRITERIA

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

F. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement in your hidradenitis suppurativa symptoms
   2. You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

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BINIMETINIB

Generic	Brand				
BINIMETINIB	MEKTOVI				

GUIDELINES FOR USE

Our guideline named **BINIMETINIB (Mektovi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

If you have unresectable or metastatic melanoma, approval also requires:
- You have a BRAF V600E or V600K mutation (types of gene mutations), as detected by a Food and Drug Administration (FDA)-approved test
- Mektovi will be used in combination with Braftovi (encorafenib)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
- Mektovi will be used in combination with Braftovi (encorafenib)

Effective: 02/01/26

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BIRCH BARK EXTRACT

Generic	Brand				
BIRCH BARK EXTRACT	FILSUVEZ				

GUIDELINES FOR USE

Our guideline named **BIRCH BARK EXTRACT (Filsuvez)** requires the following rule(s) be met for approval:

A. You have epidermolysis bullosa (EB: a type of genetic skin disorder)
B. You are 6 months of age or older
C. Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa (types of genetic skin disorders)

Effective: 01/01/25

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BLINATUMOMAB (NSA)

Generic	Brand			
BLINATUMOMAB	BLINCYTO			

GUIDELINES FOR USE

Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for approval:

You have CD19 (a type of protein)-positive B-cell precursor acute lymphoblastic leukemia (ALL: a type of blood cancer)

You meet ONE of the following:

- You have minimal residual disease (MRD)-positive acute lymphoblastic leukemia (a small number of cancer cells remain after treatment), you are in first or second complete remission (no symptoms or signs of *disease), AND* you have minimal residual disease of at least 0.1 percent
- You have relapsed or refractory acute lymphoblastic leukemia (a type of blood cancer that has returned or did not respond to treatment)
- You have Philadelphia chromosome-negative acute lymphoblastic leukemia (a type of blood cancer) AND you are in the consolidation phase (treatment following initial therapy) of multiphase chemotherapy (cancer treatment that involves multiple courses of therapy)

Effective: 07/22/24

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BORTEZOMIB (NSA)

Generic	Brand			
BORTEZOMIB	VELCADE, BORUZU, BORTEZOMIB			

GUIDELINES FOR USE

Our guideline named **BORTEZOMIB (Velcade, Boruzu)** requires the following rule(s) be met for approval:
You have ONE of the following:
Multiple myeloma (a type of blood cancer)
Mantle cell lymphoma (a type of blood cancer)
You are 18 years of age or older

Effective: 01/01/25

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BOSENTAN

Generic	Brand				
BOSENTAN	TRACLEER, BOSENTAN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 3 years of age and older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
E. You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide
F. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide

Effective: 07/01/24

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BOSUTINIB

Generic	Brand				
BOSUTINIB	BOSULIF, BOSUTINIB				

GUIDELINES FOR USE

Our guideline named **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:

A. You have Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML: a type of blood cell cancer)

B. **If you have Philadelphia chromosome-positive chronic myelogenous leukemia in chronic phase (CP), approval also requires:**
   1. You are 1 year of age or older
   2. You meet ONE of the following:
      a. You are newly diagnosed (such as you are starting or previously started Bosulif treatment at the time your condition was identified)
      b. You have a resistance (medication no longer works as well) or intolerance (side effect) to a prior therapy (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib]); you had a mutational analysis (a type of lab test) prior to the start of therapy; AND Bosulif is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

C. **If you have Philadelphia chromosome-positive chronic myelogenous leukemia in accelerated phase (AP) or blast phase (BP), approval also requires:**
   1. You are 18 years of age or older
   2. You have a resistance (medication no longer works as well) or intolerance (side effect) to a prior therapy (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib])
   3. You had a mutational analysis (a type of lab test) prior to the start of therapy; AND Bosulif is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

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BREMELANOTIDE

Generic	Brand				
BREMELANOTIDE ACETATE	VYLEESI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:
- You have acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD]) (a type of sexual disorder), as defined by ALL of the following:
  - You have persistently (continues to exist) or recurrently (continues to return) deficient (absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
  - Your HSDD (a type of sexual disorder) is NOT a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship, or the effects of a medication or drug substance
  - Your HSDD (a type of sexual disorder) symptom causes marked distress or interpersonal difficulty
- You are a premenopausal (before menopause) female
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) bupropion
- You will NOT use Vylessi concurrently (at the same time) with Addyi (flibanserin)

RENEWAL CRITERIA

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for renewal:
- You will NOT use Vyleesi concurrently (at the same time) with Addyi (flibanserin)
- You have experienced continued improvement in symptoms of hypoactive sexual desire disorder (HSDD)/female sexual interest/arousal disorder (FSIAD) (a type of sexual disorder) (such as increased sexual desire, reduced distress)

Effective: 10/01/25

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BRENSOCATIB

Generic	Brand				
BRENSOCATIB	BRINSUPRI				

GUIDELINES FOR USE

Our guideline named **BRENSOCATIB (Brinsupri)** requires the following rule(s) be met for approval:

You have non-cystic fibrosis bronchiectasis (NCFB: a condition where your lungs' airway becomes damaged, widened, and thickened)

You are 12 years of age or older

Effective: 09/08/25

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BRENTUXIMAB

Generic	Brand				
BRENTUXIMAB VEDOTIN	ADCETRIS				

GUIDELINES FOR USE

Our guideline named **BRENTUXIMAB (Adcetris)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Classical Hodgkin lymphoma (a type of blood cancer)
   2. Systemic anaplastic large cell lymphoma (a type of blood cancer)
   3. CD30-expressing peripheral T-cell lymphomas (a type of blood cancer)
   4. Primary cutaneous anaplastic large cell lymphoma (a type of blood cancer)
   5. Mycosis fungoides (a type of blood cancer affecting the skin)
   6. Large B-cell lymphoma (LBCL), which includes diffuse large B-cell lymphoma (DLBCL) not other specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL) (types of blood cancer)

B. **If you have classical Hodgkin lymphoma, approval also requires ONE of the following:**
   1. Your cancer is stage III or IV; you are 18 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine
   2. Your cancer is considered high-risk; you are 2 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
   3. You are at high risk for relapse (disease comes back) or disease progression (disease gets worse) after having autologous hematopoietic stem cell transplant (auto-HSCT) (defined as refractory [disease does not respond to treatment], relapse within 12 months, or relapse at least 12 months with extranodal [area outside of the lymph node] disease); you are 18 years of age or older; AND you have obtained complete/partial remission (little or no sign of cancer in your body), or stable disease to most recent pre-auto-HSCT salvage therapy
   4. Your cancer has relapsed; you are 18 years of age or older; AND you have failed autologous hematopoietic stem cell transplant (auto-HSCT: transplant cells are from your own body)
   5. Your cancer has relapsed; you are 18 years of age or older; you are not a candidate for auto-HSCT; AND you have failed at least two multi-agent chemotherapy regimens (such as ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

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GUIDELINES FOR USE (CONTINUED)

C. **If you have systemic anaplastic large cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have not been previously treated AND Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone
      b. Your cancer has relapsed (disease that has returned) AND you have failed at least one multi-agent chemotherapy regimen (such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

D. **If you have CD30-expressing peripheral T-cell lymphomas, including angioimmunoblastic T-cell lymphoma or peripheral T-cell lymphoma not otherwise specified, approval also requires:**
   1. You are 18 years of age or older
   2. You have not been previously treated
   3. Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

E. **If you have primary cutaneous anaplastic large cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received prior systemic therapy (treatment that targets the entire body such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], methotrexate)

F. **If you have mycosis fungoides, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is CD30 (a type of protein)-positive
   3. You have received prior systemic therapy (treatment that targets the entire body such as Istodax [romidepsin], methotrexate)

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GUIDELINES FOR USE (CONTINUED)

G. **If you have large B-cell lymphoma, which includes diffuse large B-cell lymphoma not other specified, diffuse large B-cell lymphoma arising from indolent lymphoma, or high-grade B-cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is relapsed (disease that has returned) or refractory (did not respond to treatment)
   3. Adcetris will be used in combination with Revlimid (lenalidomide) AND a rituximab product (such as Rituxan [rituximab], Truxima [rituximab-abbs])
   4. You have has tried at least two lines of systemic therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
   5. You are not eligible for autologous hematopoietic stem cell transplantation (auto-HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells) or chimeric antigen receptor (CAR) T-cell therapy (such as Yescarta [axicabtagene ciloleucel], Kymriah [tisagenlecleucel])

Effective: 03/10/25

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BRIGATINIB

Generic	Brand				
BRIGATINIB	ALUNBRIG				

GUIDELINES FOR USE

Our guideline named **BRIGATINIB (Alunbrig)** requires the following rule(s) be met for approval:
You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
You are 18 years of age or older
Your tumors are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of abnormal gene), as detected by a Food and Drug Administration (FDA)-approved test

Effective: 02/01/26

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BRODALUMAB

Generic	Brand				
BRODALUMAB	SILIQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
E. You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
F. You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Tremfya (guselkumab)
    3. Skyrizi (risankizumab-rzaa)
    4. Enbrel (etanercept)
    5. Otezla (apremilast)
    6. Taltz (ixekizumab)
    7. Sotyktu (deucravacitinib)
    8. Bimzelx (bimekizumab-bkzx)
    9. Adalimumab-ryvk/adalimumab-aaty
    10. Icotyde (icotrokinra)

(Initial criteria continued on next page)

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

H. You meet ONE of the following:
   1. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:
A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis [a type of skin condition]) of at least 50 percent or more
C. You have NOT developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq
D. You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

(Renewal criteria continued on next page)

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BRODALUMAB

RENEWAL CRITERIA (CONTINUED)

E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   2. Tremfya (guselkumab)
   3. Skyrizi (risankizumab-rzaa)
   4. Enbrel (etanercept)
   5. Otezla (apremilast)
   6. Taltz (ixekizumab)
   7. Sotyktu (deucravacitinib)
   8. Bimzelx (bimekizumab-bkzx)
   9. Adalimumab-ryvk/adalimumab-aaty
   10. Icotyde (icotrokinra)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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BROLUCIZUMAB-DBLL (NSA)

Generic	Brand				
BROLUCIZUMAB-DBLL	BEOVU				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   Neovascular (wet) age-related macular degeneration (nAMD: a type of eye disease)
   Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)

B. **If you have neovascular age-related macular degeneration, approval also requires:**
   Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Susvimo)

C. **If you have diabetic macular edema, approval also requires:**
   Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Vabysmo)

RENEWAL CRITERIA

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for renewal:

You have ONE of the following diagnoses:
   Neovascular (wet) age-related macular degeneration (nAMD: a type of eye disease)
   Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)

If you have neovascular age-related macular degeneration, renewal also requires:
   You have maintained or improved visual acuity (vision clarity or sharpness)
   You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Susvimo)

If you have diabetic macular edema, renewal also requires:
   You have maintained or improved visual acuity (vision clarity or sharpness)
   You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Vabysmo)

Effective: 10/01/22

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BUDESONIDE-EOHILIA

Generic	Brand				
BUDESONIDE	EOHILIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BUDESONIDE-EOHILIA** requires the following rule(s) be met for approval:

A. You have eosinophilic esophagitis (a type of immune system disorder)
B. You are 11 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or allergist (a type of allergy doctor)
D. You have at least 15 eosinophils/high powered field (a type of lab test) in the esophagus as confirmed by a biopsy (removal of cells or tissue from the body for examination)
E. You have tried or have a contraindication to (harmful for you to use) one inhaled corticosteroid (such as Flovent [fluticasone], Pulmicort [budesonide]) OR one proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)

RENEWAL CRITERIA

Our guideline named **BUDESONIDE-EOHILIA** requires the following rule(s) be met for renewal:

A. You have eosinophilic esophagitis (EoE: a type of immune system disorder)
B. You meet ONE of the following:
    1. You have less than 15 eosinophils/high powered field (eos/hpf: a type of lab test) in the esophagus after treatment with Eohilia
    2. You have experienced an improvement in dysphagia (difficulty swallowing) compared to baseline

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Effective: 07/01/24

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BUDESONIDE - ORTIKOS

Generic	Brand				
BUDESONIDE	ORTIKOS				

GUIDELINES FOR USE

Our guideline named **BUDESONIDE - ORTIKOS** requires the following rule(s) be met for approval:

You have mild to moderate Crohn's disease (a type of bowel disorder)

If you have mild to moderate active Crohn's disease, approval also requires:

- You are 8 years of age or older
- You have tried generic budesonide 3 mg capsules OR you cannot tolerate the pill burden associated with the generic product

If you have mild to moderate Crohn's disease, approval also requires:

- You are 18 years of age or older
- Ortikos is being used for the maintenance of clinical remission (signs and symptoms of disease have improved or disappeared)
- You have tried generic budesonide 3 mg capsules, OR you cannot tolerate the pill burden associated with the generic product

Effective: 02/01/26

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BUDESONIDE - TARPEYO

Generic	Brand				
BUDESONIDE	TARPEYO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for approval:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
D. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
E. You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (increased levels of protein in the urine, such as greater than 1 gram protein in a 24-hour urine collection or at least 1 g/g urine protein to creatinine ratio [UPCR: a test that measures the amount of protein in urine])
F. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 35 mL/min/1.73m^2
G. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

RENEWAL CRITERIA

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You have improved or stable kidney function compared to baseline (before starting Tarpeyo) OR you have a reduction in proteinuria (lowered levels of protein in the urine)

Effective: 07/15/26

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BULEVIRTIDE-GMOD

Generic	Brand				
BULEVIRTIDE ACETATE-GMOD	HEPCLUDEX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BULEVIRTIDE-GMOD (Hepcludex)** requires the following rule(s) be met for approval:

- You have chronic (long-term) hepatitis delta virus (HDV: liver inflammation caused by a type of virus)
- You are 18 years of age or older
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage or scarring)
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), physician specializing in treatment of hepatitis (liver inflammation) (such as a hepatologist [a type of liver doctor]), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes)
- You have a positive serum anti-HDV (hepatitis delta virus) antibody test (a type of blood test) OR a positive serum/plasma HDV RNA PCR (a type of blood test)

RENEWAL CRITERIA

Our guideline named **BULEVIRTIDE-GMOD (Hepcludex)** requires the following rule(s) be met for renewal:

- You have chronic (long-term) hepatitis delta virus (HDV: liver inflammation caused by a type of virus)
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage or scarring)
- You had a virological or biochemical response (measures that show Hepcludex therapy is effective, such as an undetectable HDV RNA or a decrease by 2 log10 IU/mL from baseline [a type of lab test that shows a suppressed or reduced viral load from before start of treatment] or alanine transaminase [ALT: a type of liver enzyme test] normalization or a trend towards these items)

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BUMETANIDE

Generic	Brand				
BUMETANIDE	ENBUMYST				

GUIDELINES FOR USE

Our guideline named **BUMETANIDE** (**Enbumyst**) requires the following rule(s) be met for approval:

You have edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), hepatic (liver) disease or renal (kidney) disease (including nephrotic syndrome [a type of kidney disorder])

You are 18 years of age or older

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), hepatologist (a type of liver doctor), or gastroenterologist (doctor who treats digestive conditions)

You have a contraindication to (harmful for you to use) or are unable to swallow bumetanide tablets

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Effective: 10/20/25

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BUPRENORPHINE EXTENDED-RELEASE

Generic	Brand				
BUPRENORPHINE	SUBLOCADE				

GUIDELINES FOR USE

Our guideline named **BUPRENORPHINE EXTENDED-RELEASE (Sublocade)** requires the following rule(s) be met for approval:

A. You have moderate to severe opioid use disorder (misuse of a type of pain medication)
B. You started treatment with a single dose of a transmucosal (medication that enters the body through a mucous layer like those in the mouth) buprenorphine product (such as Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]), OR you are already being treated with buprenorphine

Effective: 03/17/25

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BUROSUMAB-TWZA

Generic	Brand				
BUROSUMAB-TWZA	CRYSVITA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BUROSUMAB-TWZA (Crysvita)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. X-linked hypophosphatemia (XLH: inherited disorder with low phosphate blood levels)
   2. Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

B. **If you have X-linked hypophosphatemia, approval also requires:**
   1. Your diagnosis is confirmed by ONE of the following:
      a. You have XLH symptoms such as osteomalacia (bone softening), excessive fractures, bowed legs, impaired growth and ONE of the following:
         i. If you are less than 18 years of age, your serum phosphate level is less than 3.2 mg/dL with normal vitamin D levels
         ii. If you are 18 years of age or older, your serum phosphate level is less than 2.5 mg/dL with normal vitamin D levels
         iii. You have more than normal amount of FGF23 protein on assay (type of lab analysis)
         iv. You have a family history of X-linked hypophosphatemia
      b. You have a *PHEX* mutation (Phosphate-regulating neutral endopeptidase, X-linked) confirmed by a genotyping (type of test)
   2. You are 6 months of age or older
   3. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformities), or medical geneticist
   4. You will not be taking oral phosphate salt or active vitamin D analog supplementation with the requested medication
   5. You meet ONE of the following:
      a. You had a trial of or failure (drug did not work) to the clinical standard of care therapy: phosphate/vitamin D analog therapy (such as calcitriol, paricalcitol)
      b. Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

(Initial criteria continued on next page)

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BUROSUMAB-TWZA

INITIAL CRITERIA (CONTINUED)

C. **If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia, approval also requires:**
   1. Your diagnosis is confirmed by the following:
      a. You have symptoms of tumor-induced osteomalacia (such as osteomalacia [softening of the bones], excessive fractures, muscle weakness, fatigue, bone pain)
   2. You are 2 years of age or older
   3. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformitis), or medical geneticist
   4. Your tumors cannot be curatively resected (surgically removed) or localized
   5. You have stopped oral phosphate and/or active vitamin D analogs (such as calcitriol, paricalcitol) at least 1 week prior to starting Crysvita
   6. You meet ONE of the following:
      a. You had a trial of or failure (drug did not work) to the clinical standard of care therapy: phosphate/vitamin D analog therapy
      b. Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

RENEWAL CRITERIA

Our guideline named **BUROSUMAB-TWZA (Crysvita)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. X-linked hypophosphatemia (XLH; inherited disorder with low phosphate blood levels)
   2. Fibroblast growth factor 23 (FGF23) -related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

B. **If you have X-linked hypophosphatemia, renewal also requires:**
   1. You have achieved normal blood phosphate levels as defined by the reference range for your age

C. **If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia, renewal also requires:**
   1. You have achieved normal fasting blood phosphate levels (around or above the lower end of the reference range for age and below 5 mg/dL)

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C1 ESTERASE INHIBITOR - BERINERT

Generic	Brand				
C1 ESTERASE INHIBITOR	BERINERT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. Berinert will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
D. You will NOT use Berinert concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])
E. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema: a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        c. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        d. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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C1 ESTERASE INHIBITOR - BERINERT

RENEWAL CRITERIA

Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use Berinert concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

Effective: 07/01/26

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C1 ESTERASE INHIBITOR - CINRYZE

Generic	Brand				
C1 ESTERASE INHIBITOR	CINRYZE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 6 years of age or older
C. Cinryze will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema: a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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C1 ESTERASE INHIBITOR - CINRYZE

RENEWAL CRITERIA

Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

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C1 ESTERASE INHIBITOR - HAEGARDA

Generic	Brand				
C1 ESTERASE INHIBITOR	HAEGARDA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 6 years of age or older
C. Haegarda will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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C1 ESTERASE INHIBITOR - HAEGARDA

RENEWAL CRITERIA

Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

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C1 ESTERASE INHIBITOR - RUCONEST

Generic	Brand				
C1 ESTERASE INHIBITOR, RECOMB	RUCONEST				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. Ruconest will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
D. You will NOT use Ruconest concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])
E. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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C1 ESTERASE INHIBITOR - RUCONEST

RENEWAL CRITERIA

Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use Ruconest concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

Effective: 07/01/26

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CABOZANTINIB CAPSULE

Generic	Brand				
CABOZANTINIB S-MALATE	COMETRIQ				

GUIDELINES FOR USE

Our guideline named **CABOZANTINIB CAPSULE (Cometriq)** requires the following rule be met for approval:

You have progressive, metastatic medullary thyroid cancer (a type of thyroid cancer that has spread to other parts of the body)

Effective: 01/01/26

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CABOZANTINIB TABLET

Generic	Brand				
CABOZANTINIB S-MALATE	CABOMETYX				

GUIDELINES FOR USE

Our guideline named **CABOZANTINIB TABLET (Cabometyx)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Advanced renal cell carcinoma (RCC: a type of kidney cancer)
- Hepatocellular carcinoma (HCC: a type of liver cancer)
- Locally advanced or metastatic differentiated thyroid cancer (DTC: a type of thyroid cancer that has spread to nearby tissue/lymph nodes or to other parts of the body)
- Pancreatic neuroendocrine tumor (pNET: tumor that began in the pancreas)
- Extra-pancreatic neuroendocrine tumor (epNET: tumor that began outside of the pancreas)

If you have advanced renal cell carcinoma, approval also requires ONE of the following:
- Cabometyx will be used as a single agent (used alone)
- Cabometyx will be used in combination with Opdivo (nivolumab) or Opdivo Qvantig (nivolumab-hyaluronidase-nvhy)

If you have hepatocellular carcinoma, approval also requires:
- You have been previously treated with Nexavar (sorafenib)

If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:
- You are 12 years of age or older
- You have disease progression (worsening) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (such as Lenvima [lenvatinib])
- You are radioactive iodine-refractory (resistant to) or ineligible

If you have a pancreatic or extra-pancreatic neuroendocrine tumor, approval also requires:
- You are 12 years of age or older
- Your tumor is unresectable (unable to remove by surgery), locally advanced or metastatic (cancer that has spread to nearby tissue/lymph nodes or to other parts of the body), and well-differentiated
- Your tumor has been previously treated

Effective: 03/04/26

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CALASPARGASE PEGOL-MKNL

Generic	Brand				
CALASPARGASE PEGOL-MKNL	ASPARLAS				

GUIDELINES FOR USE

Our guideline named **CALASPARGASE PEGOL-MKNL (Asparlas)** requires the following rule(s) be met for approval:

A. You have acute lymphoblastic leukemia (ALL: a type of blood cancer)
B. You are 1 month to 21 years of age
C. Asparlas will be used as a part of a chemotherapeutic (medications used to treat cancer) plan that contains multiple medications

Effective: 02/24/25

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CANAKINUMAB

Generic	Brand				
CANAKINUMAB/PF	ILARIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cryopyrin-Associated Periodic Syndromes (CAPS: a type of immune disorder), including Familial Cold Auto-inflammatory Syndrome (FCAS: a type of immune disorder) or Muckle-Wells Syndrome (MWS: a type of immune disorder)
   2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: a type of genetic disease)
   3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (types of genetic disorders)
   4. Familial Mediterranean Fever (FMF: a type of genetic disorder)
   5. Adult-Onset Still's Disease (AOSD: an autoinflammatory disease)
   6. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   7. Gout flares (episodes of pain or swelling associated with a type of joint condition)

B. **If you have Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:**
   1. You are 4 years of age or older
   2. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
   3. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
   4. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome or Muckle-Wells Syndrome (types of immune disorders)

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have Tumor Necrosis Factor Receptor Associated Periodic Syndrome, approval also requires:**
   1. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (a type of genetic disease)

D. **If you have Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency, approval also requires:**
   1. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency (types of genetic disorders)

E. **If you have Familial Mediterranean Fever, approval also requires:**
   1. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Familial Mediterranean Fever (a type of genetic disorder)

F. **If you have Adult-Onset Still's Disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   2. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Adult-Onset Still's Disease (an autoinflammatory disease)
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kineret (anakinra)

G. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

H. **If you have gout flares, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of gout flares (episodes of pain or swelling associated with a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) ALL of the following:
      a. Colchicine
      b. An NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, indomethacin)
      c. A corticosteroid (such as triamcinolone, methylprednisolone, prednisone, prednisolone)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

NOTE: For the diagnoses of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF), please refer to the Initial Criteria section.

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Adult-Onset Still's Disease (AOSD: an autoinflammatory disease)
   2. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   3. Gout flares (episodes of pain or swelling associated with a type of joint condition)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. **If you have Adult-Onset Still's Disease, renewal also requires:**
   1. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Adult-Onset Still's Disease (an autoinflammatory disease)
   2. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis [a type of joint condition]) or you have achieved a reduction (decrease) in your corticosteroid (such as prednisone) dose
   3. Your disease is still clinically active (remission [reduction or disappearance of the signs and symptoms of a disease] has not been attained) OR discontinuing therapy will be harmful for you
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kineret (anakinra)

C. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   2. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
   3. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis [a type of joint condition])

D. **If you have gout flares, renewal also requires:**
   1. You have shown improvement of gout flares while on Ilaris
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of gout flares (episodes of pain or swelling associated with a type of joint condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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CANTHARIDIN

Generic	Brand				
CANTHARIDIN	YCANTH				

GUIDELINES FOR USE

Our guideline named **CANTHARIDIN (Ycanth)** requires the following rule(s) be met for approval:
You have molluscum contagiosum (a viral skin infection)
You are 2 years of age or older
You will NOT use Ycanth concurrently (at the same time) with another topical medication for the treatment of molluscum contagiosum (a viral skin infection) (such as Zelsuvmi [berdazimer], Condylox [podofilox])
You have tried or have a contraindication to (harmful for you to use) podofilox 0.5% topical solution

Effective: 10/01/25

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CAPECITABINE

Generic	Brand				
CAPECITABINE	XELODA, CAPECITABINE				

GUIDELINES FOR USE

Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:

You have ONE of the following:

- Stage III colon cancer (the cancer that has spread to lymph nodes)
- Locally advanced rectal cancer (cancer that has spread from where it started to nearby tissue or lymph nodes)
- Unresectable (unable to remove by surgery) or metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
- Metastatic breast cancer (the cancer that has spread to other parts of the body)
- Unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer (a type of digestive system cancer that has spread to other parts of the body)
- HER2 (a type of protein)-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
- Pancreatic adenocarcinoma (a type of cancer of the pancreas)

If you have Stage III colon cancer, approval also requires:

- The requested medication will be used as adjuvant (add-on) treatment

If you have locally advanced rectal cancer, approval also requires:

- You are 18 years of age or older
- The requested medication will be used as perioperative (the time before and after surgery) treatment
- The requested medication will be used as part of chemoradiotherapy (a type of cancer treatment)

If you have advanced or metastatic breast cancer, approval also requires ONE of the following:

- The requested medication will be used as a single agent (used alone) if an anthracycline (such as doxorubicin, daunorubicin)- or taxane (such as paclitaxel, docetaxel)-containing chemotherapy is not indicated
- The requested medication will be used in combination with docetaxel after disease progression (worsens) on prior anthracycline (such as doxorubicin, daunorubicin)-containing chemotherapy

(Criteria continued on next page)

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

If you have unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as part of a combination chemotherapy (drugs used to treat cancer) regimen

If you have HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
- You are 18 years of age or older
- You have not received prior treatment for metastatic disease
- The requested medication will be used as part of a combination regimen (such as with cisplatin, trastuzumab)

If you have pancreatic adenocarcinoma, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as adjuvant (add-on) treatment
- The requested medication will be used as part of a combination chemotherapy regimen (such as with gemcitabine)

Effective: 02/01/26

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CAPIVASERTIB

Generic	Brand				
CAPIVASERTIB	TRUQAP				

GUIDELINES FOR USE

Our guideline named **CAPIVASERTIB (Truqap)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic breast cancer (breast cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
   2. Metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (cancer that has spread to other parts of the body and has not been treated with, or may respond to, testosterone-lowering treatment)
   3. A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

B. **If you have locally advanced or metastatic breast cancer, approval also requires:**
   1. Truqap will be used together with Faslodex (fulvestrant)
   2. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, with one or more PIK3CA/AKT1/PTEN-mutations (abnormal changes in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
   3. You have experienced disease progression (worsening) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

C. **If you have metastatic androgen pathway modulation-naive or -sensitive prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Truqap will be used in combination with abiraterone (Zytiga) and prednisone
   3. Your prostate cancer is PTEN-deficient (loss of a type of gene) as detected by a Food and Drug Administration (FDA)-authorized test

Effective: 07/08/26

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CAPLACIZUMAB-YHDP

Generic	Brand				
CAPLACIZUMAB-YHDP	CABLIVI				

GUIDELINES FOR USE

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi)** requires the following rule(s) be met for approval:
You have acquired thrombotic thrombocytopenia purpura (aTTP: a type of blood disorder)
You are 12 years of age or older
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
You have NOT experienced more than TWO recurrences of acquired thrombotic thrombocytopenia purpura (aTTP: a type of blood disorder) while on Cablivi therapy. Recurrences include a new drop in platelet (type of blood cell) count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (PEX: filtering of blood) and up to 28 days of extended therapy
You also meet ONE of the following:
- Your request is for continuation of Cablivi therapy from an inpatient (hospital) setting, AND Cablivi was previously initiated as part of a Food and Drug Administration (FDA)-approved treatment regimen in combination with plasma exchange (filtering of blood) and immunosuppressive therapy (treatment that weakens the immune system) within the inpatient setting
- Your request is for continuation of Cablivi therapy after the initial 30-day treatment course (with no break in therapy) and you meet ALL of the following:
  - You are receiving immunosuppressive therapy
  - You are experiencing signs of persistent underlying disease (such as suppressed ADAMTS13 [also known as von Willebrand factor-cleaving protease (VWFCP): a type of enzyme] activity level remains present)

Effective: 01/19/26

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CARBIDOPA-LEVODOPA

Generic	Brand				
CARBIDOPA/ LEVODOPA	DUOPA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule be met for approval:
You have advanced Parkinson's disease (a type of movement disorder)
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
You are experiencing at least 3 hours of “off” time (period of symptoms in between doses) on your current Parkinson’s disease drug treatment (medication for a type of movement disorder)
You have shown a clear responsiveness to treatment with levodopa
You meet ONE of the following:
- You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
- You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

RENEWAL CRITERIA

Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule(s) be met for renewal:
You have advanced Parkinson's disease (a type of movement disorder)
You have experienced improvement in motor symptoms (ability to move)

Effective: 04/01/26

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CARBOXYMETHYLCELLULOSE-CITRIC

Generic	Brand				
CARBOXYMETHYLCELLULOSE /CITRIC	PLENITY				

GUIDELINES FOR USE

Our guideline named **CARBOXYMETHYLCELLULOSE-CITRIC (Plenity)** requires the following rule(s) be met for approval:
The request is for weight management
You are 18 years of age or older
You have a body mass index (BMI) of 25 to 40 kg/m(2)
Plenity will be used in conjunction (together) with diet and exercise

Effective: 02/01/26

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CARFILZOMIB (NSA)

Generic	Brand			
CARFILZOMIB	KYPROLIS			

GUIDELINES FOR USE

Our guideline named **CARFILZOMIB (Kyprolis)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment)
B. You are 18 years of age or older
C. You meet ONE of the following:
    1. You have previously received one or more lines of multiple myeloma therapy AND will be using Kyprolis alone
    2. You have previously received one to three lines of therapy AND will be using Kyprolis in combination with ONE of the following:
        a. Lenalidomide and dexamethasone
        b. Dexamethasone
        c. Daratumumab and dexamethasone
        d. Daratumumab-hyaluronidase-fihj and dexamethasone
        e. Isatuximab and dexamethasone

Effective: 05/01/23

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CARGLUMIC ACID

Generic	Brand				
CARGLUMIC ACID	CARBAGLU CARGLUMIC ACID				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (short-term or long-term high ammonia blood levels due to a genetic disorder)
- Acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (short-term high ammonia blood levels due to a genetic disorder)

If you have acute or chronic hyperammonemia due to N-acetylglutamate synthase deficiency, approval also requires:

- Your N-acetylglutamate synthase gene mutation (abnormal change in gene) is confirmed by biochemical or genetic testing (types of lab tests)

If you have acute hyperammonemia due to propionic acidemia, approval also requires your diagnosis is confirmed by ONE of the following:

- You have elevated methylcitric acid AND normal methylmalonic acid (substances that indicate presence of a disease)
- You had genetic testing confirming mutation in the PCCA or PCCB gene (abnormal changes in types of genes)

If you have acute hyperammonemia due to methylmalonic acidemia, approval also requires your diagnosis is confirmed by ONE of the following:

- You have elevated methylmalonic acid and methylcitric acid (substances that indicate presence of a disease)
- You had genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes (abnormal changes in types of genes)

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CARGLUMIC ACID

RENEWAL CRITERIA

NOTE: For the diagnoses of acute hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency or acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA), please refer to the Initial Criteria section.

Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for renewal:
You have chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (long-term high ammonia blood levels due to a genetic disorder)
You have clinical improvement or improved plasma (blood) ammonia levels

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Effective: 04/01/26

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CASIMERSEN

Generic	Brand				
CASIMERSEN	AMONDYS-45				

GUIDELINES FOR USE

Our guideline named **CASIMERSEN (Amondys-45)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You have a confirmed mutation in the DMD gene that is responsive to exon 45 skipping (a type of gene mutation)

Effective: 02/24/25

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CELECOXIB - ELYXYB

Generic	Brand				
CELECOXIB	ELYXYB				

GUIDELINES FOR USE

Our guideline named **CELECOXIB - ELYXYB** requires the following rule(s) be met for approval:
The request is for the acute (quick onset) treatment of migraines (type of headache)
You are 18 years of age or older
You are unable to swallow pills (such as tablets or capsules)
You have tried or have a contraindication to (harmful for you to use) the preferred medication:
generic ibuprofen oral liquid formulation

Effective: 01/01/26

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CELECOXIB-VYSCOXA

Generic	Brand				
CELECOXIB	VYSCOXA				

GUIDELINES FOR USE

Our guideline named **CELECOXIB-VYSCOXA** requires the following rule(s) be met for approval:

You have ONE of the following:
- Osteoarthritis (OA: type of joint condition)
- Rheumatoid arthritis (RA: type of joint condition)
- Ankylosing spondylitis (AS: type of joint condition)
- Juvenile rheumatoid arthritis (JRA: type of joint condition)

If you have osteoarthritis, approval also requires:
- You are 18 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation

If you have rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation

If you have juvenile rheumatoid arthritis, approval also requires:
- You are 2 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation

Effective: 11/10/25

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CEMIPLIMAB-RWLC

Generic	Brand				
CEMIPLIMAB-RWLC	LIBTAYO				

GUIDELINES FOR USE

Our guideline named **CEMIPLIMAB-RWLC (Libtayo)** requires the following rules be met for approval:

You have ONE of the following diagnoses:
- Cutaneous squamous cell carcinoma (a type of skin cancer)
- Metastatic or locally advanced basal cell carcinoma (a type of skin cancer that has spread to other parts of the body or to nearby tissue or lymph nodes)
- Non-small cell lung cancer (a type of lung cancer)

If you have cutaneous squamous cell carcinoma, approval also requires ONE of the following:
- Your cancer is metastatic or locally advanced (cancer that has spread to other parts of the body or to nearby tissue or lymph nodes) AND you are not a candidate for curative (to cure) surgery or curative radiation
- Your cancer is at high risk of recurrence (returning) after surgery and radiation AND Libtayo will be used as adjuvant (additional) treatment

If you have metastatic or locally advanced basal cell carcinoma, approval also requires:
- You have previously been treated with a hedgehog pathway inhibitor (such as Erivedge [vismodegib], Odomzo [sonidegib]) or a hedgehog pathway inhibitor is not appropriate for you

If you have non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer is metastatic (cancer that has spread to other parts of the body) OR locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes, where you are not a candidate for surgical resection [remove by surgery] or definitive chemoradiation [a type of cancer treatment])
- Your tumors do not have EGFR, ALK or ROS1 aberrations (types of abnormal genes)
- You meet ONE of the following:
  - Libtayo will be used as a single agent AND your tumors has high PD-L1 (programmed death-ligand: type of protein) expression [Tumor Proportion Score (TPS) at least 50%], as determined by a Food and Drug Administration (FDA)-approved test
  - Libtayo will be used in combination with platinum-based chemotherapy (such as carboplatin, cisplatin)

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CENEGERMIN-BKBJ

Generic	Brand				
CENEGERMIN-BKBJ	OXERVATE				

GUIDELINES FOR USE

Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:

A. You have neurotrophic keratitis (an eye disease due to a damaged eye nerve)
B. Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor)
C. You have a medical history that supports a cause for trigeminal nerve damage (damage to a nerve in the head) (such as herpes zoster infection [shingles virus], multiple sclerosis [type of nerve disorder], diabetes (a disorder with high blood sugar), ocular surgical [eye surgery] damage)
D. You have loss of corneal (a part of the eye) sensitivity, corneal epithelium changes, and/or loss of tear production
E. You are refractory (not fully responsive) to conservative management (artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)
F. You have NOT previously completed an 8-week course of Oxervate (cenegermin-bkbj) in the affected eye(s) during your lifetime

Effective: 07/29/26

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CERITINIB

Generic	Brand				
CERITINIB	ZYKADIA				

GUIDELINES FOR USE

Our guideline named **CERITINIB (Zykadia)** requires the following rule(s) be met for approval:
You have metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
You are 18 years of age or older
Your tumor is anaplastic lymphoma kinase (ALK)-positive (a type of defect in a gene) as confirmed by a Food and Drug Administration (FDA)-approved test

Effective: 02/01/26

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CERLIPONASE ALFA (NSA)

Generic	Brand			
CERLIPONASE ALFA	BRINEURA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for approval:

- You have neuronal ceroid lipofuscinosis type 2 (CLN2 disease: a type of genetic disorder), also known as tripeptidyl peptidase 1 (TPP1) deficiency (a type of genetic disorder)
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or pediatric (children) CLN2 specialist
- Your diagnosis is confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping (types of lab test)
- You are ambulatory (able to walk or crawl) and experiencing symptoms (such as instability [not able to control movement], intermittent (on-and-off) falls, needs help to walk, can crawl only)
- You have a CLN2 Clinical Rating Scale Score (a test to measure the severity of ceroid lipofuscinosis type 2) of 3 to 5, with a minimum score of 1 in each of the motor and language category

RENEWAL CRITERIA

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for renewal:

- You have improved or maintained baseline (before starting Brineura) motor function (such as ambulation [ability to move], walking, crawling) or demonstrated a less-than-expected decline in motor function (such as ambulation, walking or crawling) from baseline
- You have a ceroid lipofuscinosis type 2 (CLN2) motor score (a score to assess severity of symptoms) of at least 1 (such as you are not bedridden [not able to get out of bed] or immobile [not able to move])

Effective: 08/19/24

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CERTOLIZUMAB PEGOL

Generic	Brand				
CERTOLIZUMAB PEGOL	CIMZIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   6. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   7. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   c. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

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INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iii. Otezla (apremilast)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Taltz (ixekizumab)
      vii. Bimzelx (bimekizumab-bkzx)
      viii. Sotyktu (deucravacitinib)
      ix. Adalimumab-ryvk/adalimumab-aaty
      x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Taltz (ixekizumab)
      iii. Bimzelx (bimekizumab-bkzx)
      iv. Adalimumab-ryvk/adalimumab-aaty
      v. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

F. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Cimzia
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
   4. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   5. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor) for the same indication
   6. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Tremfya (guselkumab)
         iii. Skyrizi (risankizumab-rzaa)
         iv. Enbrel (etanercept)
         v. Otezla (apremilast)
         vi. Taltz (ixekizumab)
         vii. Sotyktu (deucravacitinib)
         viii. Bimzelx (bimekizumab-bkzx)
         ix. Adalimumab-ryvk/adalimumab-aaty
         x. Icotyde (icotrokinra)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

H. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   6. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   7. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      c. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RENEWAL CRITERIA (CONTINUED)

C. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iii. Otezla (apremilast)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Taltz (ixekizumab)
      vii. Bimzelx (bimekizumab-bkzx)
      viii. Sotyktu (deucravacitinib)
      ix. Adalimumab-ryvk/adalimumab-aaty
      x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Taltz (ixekizumab)
      iii. Bimzelx (bimekizumab-bkzx)
      iv. Adalimumab-ryvk/adalimumab-aaty
      v. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

F. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)

G. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
   2. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

(Renewal criteria continued on next page)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Tremfya (guselkumab)
      iii. Skyrizi (risankizumab-rzaa)
      iv. Enbrel (etanercept)
      v. Otezla (apremilast)
      vi. Taltz (ixekizumab)
      vii. Sotyktu (deucravacitinib)
      viii. Bimzelx (bimekizumab-bkzx)
      ix. Adalimumab-ryvk/adalimumab-aaty
      x. Icotyde (icotrokinra)

H. **If you have moderate to severe Crohn's disease, renewal also requires:**
1. You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You are pregnant, breastfeeding, or trying to become pregnant
   b. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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CETUXIMAB

Generic	Brand				
CETUXIMAB	ERBITUX				

GUIDELINES FOR USE

Our guideline named **CETUXIMAB (Erbitux)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has spread from where it started to nearby tissue or lymph nodes)
   2. Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has returned or has spread to other parts of the body)
   3. Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has returned or has spread to other parts of the body)
   4. Metastatic colorectal cancer (mCRC: a type of digestive system cancer that has spread to other parts of the body)

B. **If you have locally or regionally advanced squamous cell carcinoma of the head and neck, approval also requires:**
   1. Erbitux will be used in combination with radiation therapy

C. **If you have recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
   1. Erbitux will be used in combination with platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin) and 5-fluorouracil (5-FU)

D. **If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
   1. You have previously failed platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin)

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

E. **If you have metastatic colorectal cancer (mCRC), approval also requires ONE of the following:**
   1. Erbitux will be used in combination with Krazati (adagrasib)
   2. Your cancer is KRAS wild-type (a type of gene with no mutation), epidermal growth factor receptor (EGFR)-expressing, as determined by a Food and Drug Administration (FDA)-approved test, AND you meet ONE of the following:
      a. Erbitux will be used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin)
      b. Erbitux will be used in combination with irinotecan and you are refractory (resistant) to irinotecan-based chemotherapy
      c. You have failed oxaliplatin-based and irinotecan-based chemotherapy OR you are intolerant to irinotecan
   3. Your cancer has a BRAF V600E mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test, and you meet ALL of the following:
      a. You are 18 years of age or older
      b. You meet ONE of the following:
         i. Erbitux will be used in combination with Braftovi (encorafenib) and fluorouracil-based chemotherapy (such as mFOLFOX6 [fluorouracil, leucovorin and oxaliplatin], FOLFIRI [fluorouracil, leucovorin, and irinotecan])
         ii. Erbitux will be used in combination with Braftovi (encorafenib), and you have previously received treatment (such as irinotecan)

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CHENODIOL

Generic	Brand				
CHENODIOL	CHENODAL, CTEXLI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CHENODIOL (Chenodal, Ctexli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cerebrotendinous xanthomatosis (a type of genetic disorder)
   2. Radiolucent gallstone(s) (hardened deposits of bile in the gall bladder that are barely seen on X-rays [a type of imaging test])

B. **If you have radiolucent gallstone(s), approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care agent: ursodiol
   2. You have NOT previously received chenodiol therapy for more than a total of 24 months
   3. Your request is for Chenodal

RENEWAL CRITERIA

Our guideline named **CHENODIOL (Chenodal, Ctexli)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Cerebrotendinous xanthomatosis (a type of genetic disorder)
   2. Radiolucent gallstone(s) (hardened deposits of bile in the gall bladder that are barely seen on X-rays [a type of imaging test])

B. **If you have cerebrotendinous xanthomatosis, renewal also requires:**
   1. You have experienced improvement as defined by ONE of the following:
      a. Normalization of elevated (high levels of) serum (blood) or urine bile alcohols (a type of bile acid)
      b. Normalization of elevated (high levels of) serum (blood) cholestanol (a type of fat) levels
      c. Improvement in neurologic and psychiatric symptoms (dementia [a type of memory disorder], pyramidal tract [a nerve pathway in the brain] and cerebellar [brain] signs)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have radiolucent gallstone(s), renewal also requires:**
   1. You have NOT previously received chenodiol therapy for more than a total of 24 months
   2. You have NOT experienced complete gallstone dissolution (breaking down) or zero gallstone dissolution, as seen on imaging (such as oral cholecystogram, ultrasonogram [types of imaging tests]) after 12 months of therapy
   3. You HAVE experienced partial gallstone dissolution (breaking down), as seen on imaging (such as oral cholecystogram, ultrasonogram [types of imaging tests]) after 12 months of therapy
   4. Your request is for Chenodal

Effective: 07/22/26

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CHOLIC ACID

Generic	Brand				
CHOLIC ACID	CHOLBAM				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for approval:
You have ONE of the following:
- A bile acid synthesis disorder (a type of rare genetic condition)
- A peroxisomal disorder (Zellweger spectrum disorder) (a type of rare genetic condition)

Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a doctor who treats digestive conditions)
You show signs or symptoms of liver disease, steatorrhea (excess fat in feces), or complications from your body not being able to absorb fat-soluble vitamins

RENEWAL CRITERIA

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- A bile acid synthesis disorder (a type of rare genetic condition)
- A peroxisomal disorder (Zellweger spectrum disorder) (a type of rare genetic condition)

You have experienced an improvement in your liver function as defined by ONE of the following:
- Your ALT (alanine aminotransferase: a type of liver enzyme) or AST (aspartate transaminase: a type of liver enzyme) values have been reduced to less than 50 U/L or your baseline (before treatment) levels have been reduced by 80 percent
- Your total bilirubin value (a type of lab test) has been reduced to less than 1 mg/dL
- There is no evidence of cholestasis (condition where bile flow from the liver is reduced/blocked) on liver biopsy (removal of cells or tissue from the body for examination)

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CIPAGLUCOSIDASE ALFA-ATGA

Generic	Brand				
CIPAGLUCOSIDASE ALFA-ATGA	POMBILITI				

GUIDELINES FOR USE

Our guideline named **CIPAGLUCOSIDASE ALFA-ATGA (Pombiliti)** requires the following rule(s) be met for approval:

A. You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA deficiency) (a type of genetic disorder)
B. You are 18 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. You are NOT improving on your current enzyme replacement therapy (ERT) (such as Lumizyme [alglucosidase alfa])
E. Pombiliti will be used in combination with Opfolda (miglustat)

Effective: 05/13/26

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CLADRIBINE

Generic	Brand				
CLADRIBINE	MAVENCLAD				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) and active secondary progressive MS (advanced disease)

You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for renewal:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) and active secondary progressive MS (advanced disease)

You have NOT received a total of two years of Mavenclad treatment (two yearly treatment courses of two cycles in each)

Effective: 04/01/26

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CLASCOTERONE

Generic	Brand				
CLASCOTERONE	WINLEVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
You have acne vulgaris (a type of skin condition)
You are 12 years of age or older
You will NOT use Winlevi at the same time with other acne therapies that are only available as brand name (such as Aklief, Cabtreo)

RENEWAL CRITERIA

Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for renewal:
You have acne vulgaris (a type of skin condition)
You have had an improvement in acne lesions
You will NOT use Winlevi at the same time with other acne therapies that are only available as brand name (such as Aklief, Cabtreo)

Effective: 01/01/26

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CLONIDINE

Generic	Brand				
CLONIDINE HCL	JAVADIN				

GUIDELINES FOR USE

Our guideline named **CLONIDINE (Javadin)** requires the following rule(s) be met for approval:
You have hypertension (high blood pressure)
You are 18 years of age or older
You have a contraindication to (harmful for you to use) or are unable to swallow clonidine tablets

Effective: 12/15/25

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COBIMETINIB

Generic	Brand				
COBIMETINIB FUMARATE	COTELLIC				

GUIDELINES FOR USE

Our guideline named **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
- Hystiocytic neoplasm (a type of white blood cell disorder)

If you have unresectable or metastatic melanoma, approval also requires:

- You are 18 years of age or older
- Your tumor has a BRAF V600E OR V600K mutation (a type of abnormal gene)
- Cotellic will be used in combination with vemurafenib (Zelboraf)

If you have a histiocytic neoplasm, approval also requires:

- You are 18 years of age or older

Effective: 02/01/26

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COLCHICINE - GLOPERBA

Generic	Brand				
COLCHICINE	GLOPERBA				

GUIDELINES FOR USE

Our guideline named **COLCHICINE - GLOPERBA** requires the following rule(s) be met for approval:

A. You have gout flares (episodes of pain or swelling associated with a type of joint condition)
B. Gloperba will be used for the prophylaxis (preventive) of gout flares (episodes of pain or swelling associated with a type of joint condition)
C. You have a contraindication to (harmful for you to use) or are unable to swallow colchicine tablets

Effective: 07/01/26

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COLLAGENASE TOPICAL

Generic	Brand				
COLLAGENASE CLOSTRIDIUM HIST.	SANTYL				

GUIDELINES FOR USE

Our guideline named **COLLAGENASE TOPICAL (Santyl)** requires the following rule(s) be met for approval:

You have chronic dermal (skin) ulcer(s) or severe burn(s) that require(s) debridement (removal of damaged tissue from a wound)

If the requested quantity is more than one tube (30 grams), approval also requires:

The higher quantity is based on the size of your wound (width/length) and the anticipated duration of therapy, using the Santyl dosing calculator (https://santyl.com/hcp/dosing)

Effective: 02/01/26

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CONCIZUMAB-MTCI

Generic	Brand				
CONCIZUMAB-MTCI	ALHEMO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CONCIZUMAB-MTCI (Alhemo)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
- Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

You are 12 years of age or older
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])

RENEWAL CRITERIA

Our guideline named **CONCIZUMAB-MTCI (Alhemo)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
- Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])
You have shown a clinical benefit compared to baseline (before starting Alhemo)

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

Generic	Brand				
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER	DEXCOM G4, DEXCOM G5 , MINIMED APP MANAGER				
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, EVERSENSE SMART TRANSMITTER, EVERSENSE E3 SMART TRANSMITTER, EVERSENSE 365 TRANSMITTER, GUARDIAN CONNECT TRANSMITTER, GUARDIAN LINK 3 TRANSMITTER, GUARDIAN 4 TRANSMITTER				
BLOOD-GLUCOSE SENSOR	DEXCOM G5-G4 SENSOR, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3, GUARDIAN 4 GLUCOSE SENSOR, EVERSENSE SENSOR-HOLDER, EVERSENSE E3 SENSOR-HLDR, EVERSENSE 365 SENSOR, MINIMED INSTINCT SENSOR, SIMPLERA SENSOR, SIMPLERA SYNC SENSOR				

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for approval:

A. You have type 1, type 2, or gestational (during pregnancy) diabetes (a disorder with high blood sugar)
B. You have tried or have a contraindication to (harmful for you to use) one of the preferred products: Dexcom G7 or Freestyle Libre, OR both products are not compatible with your current insulin pump
C. You meet ONE of the following:
    1. You are being treated with insulin (such as Humalog [insulin lispro], Lantus [insulin glargine])
    2. You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes)
D. **If you are requesting Dexcom G4 or Dexcom G5 system (meter, sensor, transmitter), or Minimed Instinct (sensor, receiver), approval also requires:**
    1. You are 2 years of age or older
E. **If you are requesting Guardian Connect (sensor, transmitter), approval also requires:**
    1. You are 14 to 75 years of age
F. **If you are requesting Guardian 3 (sensor, link transmitter), Guardian 4 (sensor, transmitter), Simplera Sensor, or Simplera Sync Sensor, approval also requires:**
    1. You are 7 years of age or older
G. **If you are requesting Eversense (sensor, smart transmitter), Eversense E3 (sensor, smart transmitter) or Eversense 365 (sensor, transmitter), approval also requires:**
    1. You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for renewal:

A. You continue to require continuous glucose monitoring

Effective: 08/08/26

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CONTINUOUS GLUCOSE MONITORS STEP OVERRIDE

Generic	Brand				
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER, FLASH GLUCOSE SCANNING READER	DEXCOM G6, G7 RECEIVER, FREESTYLE LIBRE 2, 3, 10, 14 READER				
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G6 TRANSMITTER				
BLOOD-GLUCOSE SENSOR, CONTINUOUS GLUCOSE SYSTEM SENSOR	DEXCOM G6, G7 SENSOR, DEXCOM G7 15 DAY SENSOR, FREESTYLE LIBRE 2, 3 PLUS SENSOR				
FLASH GLUCOSE SENSOR, BLOOD GLUCOSE SENSOR	FREESTYLE LIBRE 2, 3, 10, 14 SENSOR				

GUIDELINES FOR USE

Our guideline named **CONTINUOUS GLUCOSE MONITORS STEP OVERRIDE** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are being treated with insulin (such as Humalog [insulin lispro], Lantus [insulin glargine])
   2. You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes [a disorder with high blood sugar])
   3. You are currently stable on the requested agent

Effective: 05/16/26

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COPPER

Generic	Brand				
COPPER HISTIDINATE	ZYCUBO				

GUIDELINES FOR USE

Our guideline named **COPPER (Zycubo)** requires the following rule(s) be met for approval:
You have Menkes disease (a type of genetic disorder)
You are 17 years of age or younger

Effective: 02/07/26

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CORTICOTROPIN

Generic	Brand				
CORTICOTROPIN	ACTHAR , ACTHAR SELFJECT, CORTROPHIN				

GUIDELINES FOR USE

Our guideline named **CORTICOTROPIN (Acthar, Cortrophin)** requires the following rule(s) be met for approval:

A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
B. You are less than 2 years of age
C. Your request is for Acthar or Cortrophin vial

Acthar or Cortrophin vial will not be approved for any other indication other than infantile spasms. Acthar or Cortrophin have not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

Acthar pre-filled SelfJect or Cortrophin pre-filled syringe will not be approved for infantile spasms (not Food and Drug Administration [FDA]-indicated) or any other indication. Acthar or Cortrophin have not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

Effective: 04/07/25

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COSIBELIMAB-IPDL

Generic	Brand				
COSIBELIMAB-IPDL	UNLOXCYT				

GUIDELINES FOR USE

Our guideline named **COSIBELIMAB-IPDL (Unloxcyt)** requires the following rule(s) be met for approval:

You have metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) (a type of skin cancer that has spread to other parts of the body or to nearby tissue or lymph nodes)

You are 18 years of age or older

You are not a candidate for curative (cure) surgery or curative radiation

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Effective: 09/15/25

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CRINECERFONT

Generic	Brand				
CRINECERFONT	CRENESSITY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CRINECERFONT (Crenessity)** requires the following rule(s) be met for approval:
You have classic congenital adrenal hyperplasia (CAH: a type of rare genetic condition)
You are 4 years of age or older
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
Crenessity will be used as adjunctive (additional) treatment with glucocorticoid (a type of steroid medication) replacement therapy
If the request is for Crenessity solution, approval also requires:
You are unable to swallow Crenessity capsules

RENEWAL CRITERIA

Our guideline named **CRINECERFONT (Crenessity)** requires the following rule(s) be met for renewal:
You have classic congenital adrenal hyperplasia (CAH: a type of rare genetic condition)
You have experienced a clinical benefit (such as decreased androstenedione levels [a type of lab test], reduction in glucocorticoid [a type of steroid medication] daily dose from baseline [before treatment], improvement in or stabilization of congenital adrenal hyperplasia [a type of rare genetic condition] symptoms)

Effective: 04/29/26

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CRISABOROLE

Generic	Brand				
CRISABOROLE	EUCRISA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CRISABOROLE (Eucrisa)** requires the following rule(s) be met for approval:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
    2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

RENEWAL CRITERIA

Our guideline named **CRISABOROLE (Eucrisa)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

Effective: 05/20/26

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CRIZANLIZUMAB-TMCA (NSA)

Generic	Brand			
CRIZANLIZUMAB-TMCA	ADAKVEO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for approval:
You have sickle cell disease (type of red blood cell disorder)
You are at least 16 years old
The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
You have previously tried hydroxyurea, unless there is a medical reason why you cannot (contraindication)
If you are 18 years of age or older, approval also requires ONE of the following:
- You had at least 2 sickle cell crises in the past year. (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered (given into the vein) narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
- You are having sickle cell associated symptoms (such as pain or anemia) which are interfering with activities of daily living
- You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever and low oxygen levels)

RENEWAL CRITERIA

Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for renewal:
You have sickle cell disease (type of red blood cell disorder)
You have maintained or experienced a reduction in acute (sudden and severe) complications of sickle cell disease (SCD) (such as a reduction in number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever and low oxygen levels]).

Effective: 04/01/20

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CRIZOTINIB

Generic	Brand				
CRIZOTINIB	XALKORI				

GUIDELINES FOR USE

Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
- Relapsed (disease that has returned) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: a type of blood cell cancer)
- Unresectable (unable to remove by surgery), recurrent, or refractory (disease does not respond to treatment) inflammatory myofibroblastic tumor (IMT: a rare type of tumor)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive or ROS1 (a type of gene)-positive as detected by a Food and Drug Administration (FDA)-approved test

If you have relapsed or refractory systemic anaplastic large cell lymphoma, approval also requires:
- You are 1 year of age or older
- Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

If you have unresectable, recurrent, or refractory inflammatory myofibroblastic tumor, approval also requires:
- You are 1 year of age or older
- Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

If the request is for Xalkori oral pellets, approval also requires:
- You are unable to swallow capsules

Effective: 02/01/26

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CROVALIMAB-AKKZ (NSA)

Generic	Brand				
CROVALIMAB-AKKZ	PIASKY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CROVALIMAB-AKKZ (Piasky)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 13 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
E. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
F. You have tried and failed (as shown by hemoglobin [type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Ultomiris (ravulizumab-cwvz)
G. You will NOT use Piasky concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

RENEWAL CRITERIA

Our guideline named **CROVALIMAB-AKKZ (Piasky)** requires the following rule(s) be met for renewal:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You have experienced a clinical benefit (such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [an enzyme] and hemoglobin [type of protein in red blood cells] levels) compared to baseline (before you started treatment)
C. You will NOT use Piasky concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

Effective: 08/05/24

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CYCLOSPORINE - VERKAZIA

Generic	Brand				
CYCLOSPORINE	VERKAZIA				

GUIDELINES FOR USE

Our guideline named **CYCLOSPORINE - VERKAZIA** requires the following rule(s) be met for approval:

You have vernal keratoconjunctivitis (allergic eye disease)

Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)

You have tried or have a contraindication to (harmful for you to use) TWO clinical standard of care medications: ophthalmic dual-acting mast cell stabilizer/antihistamines (such as ketotifen), mast cell stabilizers (such as cromolyn)

Effective: 04/01/26

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CYCLOSPORINE - VEVYE

Generic	Brand				
CYCLOSPORINE	VEVYE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for approval:

A. You have dry eye disease (DED: a type of eye condition)
B. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
C. You have at least ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
D. You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: an ocular lubricant (such as carboxymethylcellulose [such as Refresh, Celluvisc, TheraTears], polyvinyl alcohol [such as LiquiTears, Refresh Classic], wetting agent [such as Systane, Lacri-Lube])
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Miebo (perfluorohexyloctane), Restasis (cyclosporine), Xiidra (lifitegrast), Tyrvaya (varenicline), Tryptyr (acoltremon)

RENEWAL CRITERIA

Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for renewal:

A. You have dry eye disease (DED: a type of eye condition)
B. You have demonstrated improvement of your dry eye disease (the treatment is working)

Effective: 07/01/26

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CYSTEAMINE BITARTRATE

Generic	Brand				
CYSTEAMINE BITARTRATE	PROCYSBI				

GUIDELINES FOR USE

Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:
You have nephropathic cystinosis (a type of genetic disease)
You are 1 year of age or older
You have tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

Effective: 02/01/26

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CYSTEAMINE HYDROCHLORIDE

Generic	Brand				
CYSTEAMINE HCL	CYSTARAN, CYSTADROPS				

GUIDELINES FOR USE

Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran, Cystadrops)** requires the following rule(s) be met for approval:
You have cystinosis (a type of genetic disorder)
You have corneal cystine crystal accumulation or deposits (buildup of a type of amino acid in the eye)

Effective: 02/01/26

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DABIGATRAN

Generic	Brand				
DABIGATRAN ETEXILATE MESELATE	PRADAXA				

GUIDELINES FOR USE

Our guideline named **DABIGATRAN (Pradaxa)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of a venous thromboembolic event (VTE: blood clot in the veins)
   2. To reduce the risk of venous thromboembolic event recurrence (happening again)

B. **If the request is for the treatment of a venous thromboembolic event, approval also requires:**
   1. You have been treated with a parenteral (injected into the vein) anticoagulation medication (type of medication to prevent blood clots) for at least 5 days
   2. You meet ONE of the following:
      a. You are 3 months to 7 years of age
      b. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules
   3. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: rivaroxaban (Xarelto) suspension AND Eliquis (apixaban) sprinkle capsules/tablets oral suspension

C. **If the request is to reduce the risk of venous thromboembolic event recurrence, approval also requires:**
   1. You have been previously treated
   2. You meet ONE of the following:
      a. You are 3 months to 7 years of age
      b. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules
   3. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: rivaroxaban (Xarelto) suspension AND Eliquis (apixaban) sprinkle capsules/tablets oral suspension

Effective: 07/01/26

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DABRAFENIB

Generic	Brand				
DABRAFENIB MESYLATE	TAFINLAR				

GUIDELINES FOR USE

Our guideline named **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
- Melanoma (a type of skin cancer)
- Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
- Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes, or it has spread to other parts of the body)
- Unresectable or metastatic solid tumor (tumor that cannot be completely removed by surgery or has spread to other parts of the body)
- Low-grade glioma (LGG: a type of brain cancer)

If you have unresectable or metastatic melanoma, approval also requires ONE of the following:
- You have a BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test AND Tafinlar will be used as a single agent (by itself)
- You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by a Food and Drug Administration (FDA)-approved test AND Tafinlar will be used in combination with Mekinist (trametinib)

If you have melanoma, approval also requires:
- You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by a Food and Drug Administration (FDA)-approved test
- Tafinlar has not previously been used for more than one year
- Tafinlar will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
- There is involvement of lymph node(s) following complete resection (removal by surgery)

If you have metastatic non-small cell lung cancer, approval also requires:
- You have a BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
- Tafinlar will be used in combination with Mekinist (trametinib)

(Criteria continued on next page)

CONTINUED ON NEXT PAGE

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
- You have a BRAF V600E mutation (type of gene mutation)
- Tafinlar will be used in combination with Mekinist (trametinib)
- You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

If you have an unresectable or metastatic solid tumor, approval also requires:
- You are 1 year of age or older
- You have a BRAF V600E mutation (type of gene mutation)
- Tafinlar will be used in combination with Mekinist (trametinib)
- Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

If you have low-grade glioma, approval also requires:
- You are 1 to 17 years of age
- You have a BRAF V600E mutation (type of gene mutation)
- Tafinlar will be used in combination with Mekinist (trametinib)
- You require systemic therapy (treatment that targets the entire body)

If the request is for the tablet for oral suspension, approval also requires:
- You cannot swallow Tafinlar (dabrafenib) capsules

Effective: 02/01/26

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DACOMITINIB

Generic	Brand				
DACOMITINIB	VIZIMPRO				

GUIDELINES FOR USE

Our guideline named **DACOMITINIB (Vizimpro)** requires the following rule(s) be met for approval:

You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

Your tumor has epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletion or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

You will NOT use Vizimpro concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

Effective: 02/01/26

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DALFAMPRIDINE

Generic	Brand				
DALFAMPRIDINE	AMPYRA, DALFAMPRIDINE ER				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:
You have multiple sclerosis (MS: a type of nerve disorder)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
You have symptoms of a walking disability (such as mild to moderate bilateral [both sides] lower extremity weakness, unilateral [one side] weakness with lower extremity or truncal ataxia [impaired balance or coordination])

RENEWAL CRITERIA

Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:
You have multiple sclerosis (MS: a type of nerve disorder)
You have experienced or maintained at least a 15% improvement in walking ability

Effective: 02/01/26

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DANICOPAN

Generic	Brand				
DANICOPAN	VOYDEYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. You will use Voydeya for the treatment of extravascular hemolysis (EVH: break down of blood cells outside of your blood stream)
E. You have anemia (a hemoglobin [Hgb: a type of protein in red blood cells] level less than or equal to 9.5 g/dL) with an absolute reticulocyte (immature red blood cell) count of at least 120 x 10(9)/L
F. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
G. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Fabhalta (iptacopan)
H. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
I. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

RENEWAL CRITERIA

Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for renewal:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You have experienced a clinical benefit (such as an improvement in hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before you started treatment)
C. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
D. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

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DAPRODUSTAT

Generic	Brand				
DAPRODUSTAT	JESDUVROQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for approval:
You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
You are 18 years of age or older
You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 4 months
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic (long-term) kidney disease (CKD)
You will NOT use Jesduvroq concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Vafseo [vadadustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])
If you are NOT currently being treated with an erythropoiesis-stimulating agent (ESA: medications used to treat anemia such as Epogen, Procrit), approval also requires:
You have a hemoglobin level (a type of blood test) of less than 11 g/dL
If you are currently being treated with an erythropoiesis-stimulating agent (ESA: medications used to treat anemia such as Epogen, Procrit), approval also requires:
You have a hemoglobin level (a type of blood test) of less than 12 g/dL
You will discontinue erythropoiesis-stimulating agent (ESA) therapy (such as Epogen [epoetin alfa], Procrit [epoetin alfa]) before starting Jesduvroq

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DAPRODUSTAT

RENEWAL CRITERIA

Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for renewal:

You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)

You have a hemoglobin level (a type of blood test) of at least 10 g/dL OR your hemoglobin level has increased by at least 2 g/dL from your baseline level (before treatment)

You will NOT use Jesduvroq concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Vafseo [vadadustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

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DARATUMUMAB (NSA)

Generic	Brand			
DARATUMUMAB	DARZALEX			

GUIDELINES FOR USE

Our guideline named **DARATUMUMAB (Darzalex)** requires the following rule(s) be met for approval:
You have multiple myeloma (plasma cell cancer)
You are 18 years of age or older
You meet **ONE** of the following criteria:

- You have newly diagnosed multiple myeloma and are not eligible for autologous stem cell transplant (cells from your own body) and will receive daratumumab in combination with lenalidomide and dexamethasone
- You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received at least one prior therapy **AND** will receive daratumumab in combination with lenalidomide and dexamethasone
- You are newly diagnosed with multiple myeloma, not eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, melphalan and prednisone
- You are newly diagnosed with multiple myeloma, are eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, thalidomide and prednisone
- You have received at least one prior therapy **AND** will receive daratumumab in combination with bortezomib and dexamethasone
- You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received one to three prior lines of therapy **AND** will receive daratumumab in combination with carfilzomib and dexamethasone
- You have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI: class of drug for myeloma cancer) **AND** will receive daratumumab in combination with pomalidomide and dexamethasone
- You have received at least three prior lines of therapy, including a proteasome inhibitor (class of drug for myeloma) and an immunomodulatory agent (drug that changes the immune response or the functioning of the immune system) **AND** you will receive daratumumab as monotherapy (single drug to treat condition)
- You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent **AND** will receive daratumumab as monotherapy

Note: Proteasome inhibitors examples include: bortezomib, carfilzomib, or ixazomib and Immunomodulatory agent examples include: lenalidomide, pomalidomide, or thalidomide.

Effective: 04/10/21

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DARATUMUMAB-HYALURONIDASE-FIHJ

Generic	Brand				
DARATUMUMAB-HYALURONIDASE-FIHJ	DARZALEX FASPRO				

GUIDELINES FOR USE

Our guideline named **DARATUMUMAB-HYALURONIDASE-FIHJ (Darzalex Faspro)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Multiple myeloma (a type of blood cancer)
- Newly diagnosed light chain (AL) amyloidosis (a buildup of proteins in the tissues causing organ dysfunction)

You are 18 years of age or older
If you have multiple myeloma, approval also requires ONE of the following:
- Your disease is newly diagnosed and you meet ONE of the following:
  - You are NOT eligible for an autologous stem cell transplant (a type of procedure to replace damaged bone marrow with cells from your own body) and you meet ONE of the following:
    - You will use Darzalex Faspro in combination with bortezomib (Velcade), melphalan, and prednisone
    - You will use Darzalex Faspro in combination with lenalidomide (Revlimid) and dexamethasone
    - You will use Darzalex Faspro in combination with bortezomib (Velcade), lenalidomide (Revlimid) and dexamethasone
  - You are eligible for an autologous stem cell transplant (a type of procedure to replace damaged bone marrow with cells from your own body) and you meet ONE of the following:
    - You will use Darzalex Faspro in combination with bortezomib (Velcade), lenalidomide (Revlimid), and dexamethasone for induction (start of treatment) and consolidation treatment (treatment following initial therapy)
    - You will use Darzalex Faspro in combination with bortezomib (Velcade), thalidomide (Thalomid), and dexamethasone

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

Your disease is relapsed or refractory (disease has returned or did not respond to treatment) and you meet ONE of the following:
- You have received at least one prior therapy AND you will use Darzalex Faspro in combination with lenalidomide (Revlimid) and dexamethasone
- You have received one to three prior lines of therapy AND you will use Darzalex Faspro in combination with carfilzomib (Kyprolis) and dexamethasone
- You have received at least one prior line of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Darzalex Faspro will be used in combination with Tecvayli (teclistamab-cqyv)

You have received at least one prior therapy AND you will use Darzalex Faspro in combination with bortezomib (Velcade) and dexamethasone

You have received at least one prior line of therapy, including lenalidomide (Revlimid) and a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), AND you will use Darzalex Faspro in combination with pomalidomide (Pomalyst) and dexamethasone

You will use Darzalex Faspro as monotherapy (one drug treatment) and meet ONE of the following:
- You have received at least three prior lines of therapy, including a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) AND an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
- You are refractory (disease did not respond to treatment) to both a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) AND an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
- You have high-risk smoldering multiple myeloma (the stage before active disease)

If you have newly diagnosed light chain amyloidosis, approval also requires:

You will use Darzalex Faspro in combination with bortezomib (Velcade), cyclophosphamide, and dexamethasone

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DARBEPOETIN ALFA

Generic	Brand				
DARBEPOETIN ALFA IN POLYSORBAT	ARANESP				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
- Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
- Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

If you have anemia due to chronic kidney disease, approval also requires:

- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 10g/dL
- You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:

- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level
- You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
Your hemoglobin level (a type of blood test) is less than 10g/dL
You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

RENEWAL CRITERIA

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for renewal:
You have ONE of the following:
Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
If you have anemia due to chronic kidney disease, renewal also requires:
You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

If you are an adult (you are 18 years of age or older), renewal also requires ONE of the following:
- Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level (a type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level (a type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
- Your hemoglobin level (a type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

If you are a pediatric patient (you are less than 18 years of age), renewal also requires ONE of the following:
- Your hemoglobin level (a type of blood test) is less than 10g/dL
- Your hemoglobin level (a type of blood test) has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
- Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
- You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
- Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
- You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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DAROLUTAMIDE

Generic	Brand				
DAROLUTAMIDE	NUBEQA				

GUIDELINES FOR USE

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
- Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

If you have non-metastatic castration resistant prostate cancer, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have received a bilateral orchiectomy (both testicles have been surgically removed)
  - You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
  - Nubeqa will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If you have metastatic castration-sensitive prostate cancer, approval also requires ONE of the following:
- You have received a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- Nubeqa will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Effective: 11/10/25

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DASATINIB-SPRYCEL

Generic	Brand				
DASATINIB	SPRYCEL, DASATINIB				

GUIDELINES FOR USE

Our guideline named **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)
- Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:
- You are 18 years of age or older AND you are newly diagnosed (such as you are starting or previously started treatment with the requested medication at the time your condition was identified)
- You are between 1 and 17 years of age

If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:
- You are 18 years of age or older
- You have resistance (medication no longer works) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
- You had a mutational analysis (a type of lab test) prior to the start of therapy AND the requested medication is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:
- You are 18 years of age or older AND have a resistance (medication no longer works) or intolerance (side effect) to prior therapy (such as imatinib [Gleevec] or nilotinib [Tasigna])
- You are between 1 and 17 years of age; you are newly diagnosed (such as you are starting or previously started treatment with the requested medication at the time your condition was identified); AND you will be using the requested medication in combination with chemotherapy (medications used to treat cancer)

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DASATINIB-PHYRAGO

Generic	Brand				
DASATINIB	PHYRAGO				

GUIDELINES FOR USE

Our guideline named **DASATINIB (Phyrago)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)
- Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
- You have a contraindication to (harmful for you to use) generic dasatinib
- You meet ONE of the following:
  - You are 18 years of age or older AND you are newly diagnosed (such as you are starting or previously started treatment with Phyrago at the time your condition was identified)
  - You are between 1 and 17 years of age

If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:
- You are 18 years of age or older
- You have a contraindication to (harmful for you to use) generic dasatinib
- You have resistance (medication no longer works) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
- You had a mutational analysis (a type of lab test) prior to the start of therapy AND Phyrago is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires:
- You have a contraindication to (harmful for you to use) generic dasatinib
- You meet ONE of the following:
  - You are 18 years of age or older AND have a resistance (medication no longer works) or intolerance (side effect) to prior therapy (such as imatinib [Gleevec], nilotinib [Tasigna])
  - You are between 1 and 17 years of age; you are newly diagnosed (such as you are starting or previously started treatment with Phyrago at the time your condition was identified); AND you will be using Phyrago in combination with chemotherapy (medications used to treat cancer)

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DATOPOTAMAB DERUXTECAN-DLNK

Generic	Brand				
DATOPOTAMAB DERUXTECAN-DLNK	DATROWAY				

GUIDELINES FOR USE

Our guideline named **DATOPOTAMAB DERUXTECAN-DLNK (Datroway)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic breast cancer (a type of breast cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)

B. **If you have unresectable or metastatic breast cancer, approval also requires ONE of the following:**
   1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative (IHC 0, IHC 1+, or IHC 2+/ISH- [type of lab test]) AND you had prior endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen) and chemotherapy (medications used to treat cancer) for unresectable or metastatic disease
   2. Your cancer is triple-negative (TNBC: a type of breast cancer) AND you are not a candidate for PD-1 (programmed cell death 1: a type of protein)/PD-L1 (programmed death-ligand 1: a type of protein) inhibitor therapy (such as Keytruda [pembrolizumab])

C. **If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is epidermal growth factor receptor (EGFR: a type of protein)-mutated (abnormal change in a type of gene)
   3. You have received prior epidermal growth factor receptor (EGFR: a type of protein)-directed therapy (such as Tagrisso [osimertinib]) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

Effective: 06/24/26

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DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

Generic	Brand			
DAUNORUBICIN/ CYTARABINE LIPOSOME	VYXEOS			

GUIDELINES FOR USE

Our guideline named **DAUNORUBICIN/CYTARABINE LIPOSOME (Vyxeos)** requires the following rule(s) be met for approval:

You have a new diagnosis of therapy-related acute myeloid leukemia (type of white blood cell cancer) OR acute myeloid leukemia with myelodysplasia-related changes (type of blood and bone marrow cancer that affects production of blood cells)

You are 1 year of age or older

Effective: 05/01/21

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DAXIBOTULINUMTOXINA-LANM

Generic	Brand				
DAXIBOTULINUMTOXINA-LANM	DAXXIFY				

GUIDELINES FOR USE

Our guideline named **DAXIBOTULINUMTOXINA-LANM (Daxxify)** requires the following rule(s) be met for approval:
You have cervical dystonia (a type of muscle condition)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

NOTE: This medication will NOT be approved for a cosmetic indication (for example wrinkles - glabellar lines, lateral canthal lines, forehead lines).

Effective: 10/04/25

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DECITABINE/CEDAZURIDINE

Generic	Brand				
DECITABINE/ CEDAZURIDINE	INQOVI				

GUIDELINES FOR USE

Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Myelodysplastic syndromes (MDS: a type of blood cancer)
   2. Chronic myelomonocytic leukemia (CMML: a type of blood cancer)
   3. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

B. **If you have myelodysplastic syndromes, approval also requires:**
   1. You are 18 years of age or older
   2. You have an International Prognostic Scoring System (a tool for evaluating severity of myelodysplastic syndrome) group of intermediate-1, intermediate-2, or high-risk

C. **If you have chronic myelomonocytic leukemia, approval also requires:**
   1. You are 18 years of age or older

D. **If you have acute myeloid leukemia, approval also requires:**
   1. You are newly diagnosed (such as you are starting or previously started Inqovi treatment at the time your condition was identified)
   2. Inqovi will be used in combination with Venclexta (venetoclax)
   3. You meet ONE of the following:
      a. You are 75 years of age or older
      b. You are 18 years of age or older with comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)

Effective: 06/10/26

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DEFERASIROX

Generic	Brand				
DEFERASIROX	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFERASIROX (Exjade, Jadenu, Jadenu Sprinkle)** requires the following rule(s) be met for approval:

A. You have one of the following:
   1. Chronic iron overload (too much iron in the body) due to blood transfusions (blood transfers)
   2. Thalassemia (a type of blood disorder)

B. **If you have chronic iron overload due to blood transfusions, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)
   3. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000 mcg/L (at least two lab values in the previous 3 months)

C. **If you have thalassemia, approval also requires:**
   1. You are 10 years of age or older
   2. You have chronic iron overload (too much iron in the body) resulting from non-transfusion dependent thalassemia (NTDT: type of blood disorder that does not require regular blood transfusion)
   3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)
   4. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300 mcg/L (at least two lab values in the previous 3 months)
   5. Your liver iron concentration (LIC) is at least 5 mg of iron per gram (Fe/g) of liver dry weight

D. **If your request is for Jadenu sprinkle packets, approval also requires:**
   1. You have tried one preferred medication: generic deferasirox tablet for oral suspension or deferasirox tablet

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DEFERASIROX

RENEWAL CRITERIA

Our guideline named **DEFERASIROX (Exjade, Jadenu, Jadenu Sprinkle)** requires the following rule(s) be met for renewal:

A. You have one of the following:
   1. Chronic iron overload (too much iron in the body) due to blood transfusions (blood transfers)
   2. Thalassemia (a type of blood disorder)

B. **If you have chronic Iron overload due to blood transfusions, renewal also requires:**
   1. Your serum ferritin levels (type of lab test) are regularly greater than 500 mcg/L (at least two lab values in the previous 3 months)

C. **If you have thalassemia, renewal also requires ONE of the following:**
   1. Your serum ferritin levels (type of lab test) are regularly greater than 300 mcg/L (at least two lab values in the previous 3 months)
   2. Your liver iron concentration (LIC) is at least 3 mg of iron per gram (Fe/g) of liver dry weight

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DEFERIPRONE

Generic	Brand				
DEFERIPRONE	FERRIPROX, DEFERIPRONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Thalassemia (a type of blood disorder)
   2. Sickle cell disease (a type of blood disorder)
   3. Anemia (a type of blood disorder)

B. You have transfusional iron overload (too much iron in the body caused by blood transfusions)

C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)

D. You have tried or have a contraindication to (harmful for you to use) at least ONE clinical standard of care medication: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

E. You meet ONE of the following:
   1. You are experiencing intolerable toxicities or clinically significant adverse effects, or have a contraindication to (harmful for you to use) current chelators (drugs that bind to iron): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
   2. Current chelation therapy (treatment that lowers iron levels) with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough

F. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
   1. You are 8 years of age or older

G. **If the request is for Ferriprox oral solution, approval also requires:**
   1. You are 3 years of age or older

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DEFERIPRONE

RENEWAL CRITERIA

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Thalassemia (a type of blood disorder)
   2. Sickle cell disease (a type of blood disorder)
   3. Anemia (a type of blood disorder)

B. Your serum ferritin levels (amount of iron-containing blood cell proteins) are consistently above 500 mcg/L (at least two lab values in the previous 3 months)

C. **If the request is for Ferriprox (deferiprone) tablets, approval also requires:**
   1. You are 8 years of age or older

D. **If the request is for Ferriprox oral solution, approval also requires:**
   1. You are 3 years of age or older

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DEFEROXAMINE

Generic	Brand				
DEFEROXAMINE MESYLATE	DESFERAL MESYLATE, DEFEROXAMINE MESYLATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:
You have transfusional iron overload (too much iron in the body caused by blood transfusions) with chronic (long-term) anemia (a type of blood disorder)
You are 3 years of age or older
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)
Your serum ferritin levels (type of lab test) are consistently greater than 1000 mcg/L (at least two lab values in the previous 3 months)

RENEWAL CRITERIA

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for renewal:
You have transfusional iron overload (too much iron in the body caused by blood transfusions) with chronic (long-term) anemia (type of blood disorder)
Your serum ferritin levels (type of lab test) are consistently greater than 500 mcg/L (at least two lab values in the previous 3 months)

Effective: 02/01/26

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DEFLAZACORT

Generic	Brand				
DEFLAZACORT	EMFLAZA, DEFLAZACORT, JAYTHARI, KYMBEE, PYQUVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFLAZACORT (Emflaza, Jaythari, Kymbee, Pyquvi)** requires the following rule(s) be met for approval:
You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
You are 2 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD: a type of muscle disorder) at a DMD treatment center
Your diagnosis of Duchenne muscular dystrophy (DMD: a type of muscle disorder) is confirmed by genetic testing
You have tried prednisone or prednisolone for at least 6 months
You meet ONE of the following:
- Prednisone or prednisolone did not work for you, and you meet **ALL** of the following:
  - You are not in Stage 1 of the disease (the pre-symptomatic phase)
  - There is no steroid myopathy (muscle disease due to steroid use)
  - You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician], pulmonary function [forced vital capacity, lung function tests], upper limb strength [moving a wheelchair 30 feet])
- You have experienced a significant adverse effect (such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

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DEFLAZACORT

RENEWAL CRITERIA

Our guideline named **DEFLAZACORT (Emflaza, Jaythari, Kymbee, Pyquvi)** requires the following rule(s) be met for renewal:
You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
If you are currently ambulatory (can walk), approval also requires:
You have shown function or improvement since being on the requested medication as measured by a standard set of ambulatory or functional status measures (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician])
If you are currently non-ambulatory (cannot walk), approval also requires:
You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since being on the requested medication as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength measures [moving in a wheelchair 30 feet], Physician Global Assessment [PGA: an evaluation by a physician])

Effective: 12/01/25

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DELAFLOXACIN

Generic	Brand				
DELAFLOXACIN MEGLUMINE	BAXDELA				

GUIDELINES FOR USE

Our guideline named **DELAFLOXACIN (Baxdela)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. Baxdela is prescribed by or in consultation with an infectious disease (ID) specialist (a doctor who specializes in the treatment of infections)
   2. You have an acute bacterial skin or skin structure infection (ABSSSI: a type of skin condition)
   3. You have community-acquired bacterial pneumonia (CABP: a type of lung infection)

B. **If you have an acute bacterial skin or skin structure infection, approval also requires:**
   1. You are 18 years of age or older
   2. Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on): *Staphylococcus aureus* (including methicillin-resistant [MRSA] *and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, or Pseudomonas aeruginosa*
   3. You are NOT using Baxdela for an animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection (infection caused by high blood sugar), decubitus ulcer formation (a type of skin injury), myonecrosis (dead muscle tissue) or ecthyma gangrenosum (a type of skin lesion)
   4. You meet ONE of the following:
      a. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
         i. The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to ONE standard of care medication for acute bacterial skin or skin structure infections (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin)
         ii. Baxdela will work against the bacteria

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

b. If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin), a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin)

C. **If you have community-acquired bacterial pneumonia, approval also requires:**
1. You are 18 years of age or older
2. Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae
3. You meet ONE of the following:
   a. Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
   b. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
      i. The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
      ii. Baxdela will work against the bacteria
   c. If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO clinical standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

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DELGOCITINIB

Generic	Brand				
DELGOCITINIB	ANZUPGO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DELGOCITINIB (Anzupgo)** requires the following rule(s) be met for approval:

A. You have moderate to severe chronic hand eczema (CHE: a type of skin condition)
B. You are 18 years of age or older
C. You have a modified Investigator's Global Assessment for Chronic Hand Eczema (IGA-CHE: a tool for evaluating the severity of your condition) score of 3 or 4
D. You have tried, or have a contraindication to (harmful for you to use), either the clinical standard of care medication: a topical corticosteroid of medium potency or greater (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Eucrisa (crisaborole), Opzelura (ruxolitinib), Zoryve (roflumilast) 0.15% cream, Vtama (tapinarof)
F. You will NOT use Anzupgo concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
    1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
    2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
    3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
    4. Potent immunosuppressants (such as azathioprine, cyclosporine)

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DELGOCITINIB

RENEWAL CRITERIA

Our guideline named **DELGOCITINIB (Anzupgo)** requires the following rule(s) be met for renewal:

A. You have moderate to severe chronic hand eczema (CHE: a type of skin condition)
B. You have had improvement of symptoms
C. You will NOT use Anzupgo concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
    1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
    2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
    3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
    4. Potent immunosuppressants (such as azathioprine, cyclosporine)

Effective: 05/20/26

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DENILEUKIN DIFTITOX-CXDL

Generic	Brand				
DENILEUKIN DIFTITOX-CXDL	LYMPHIR				

GUIDELINES FOR USE

Our guideline named **DENILEUKIN DIFTITOX-CXDL (Lymphir)** requires the following rule(s) be met for approval:

You have Stage I-III cutaneous T-cell lymphoma (CTCL: a type of blood cancer that affects the skin)

You are 18 years of age or older

You have relapsed or refractory disease (disease that has returned or did not respond to treatment)

You have received at least one prior systemic therapy (treatment that targets the entire body such as methotrexate/pralatrexate, retinoids [such as acitretin, isotretinoin])

Effective: 12/22/25

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DENOSUMAB-BMWO-OSENVELT

Generic	Brand				
DENOSUMAB-BMWO	OSENVELT				

GUIDELINES FOR USE

Our guideline named **DENOSUMAB-BMWO-OSENVELT** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Bone metastases from a solid tumor (tumor has spread to the bone)
   3. Giant cell tumor of bone (noncancerous tumor)
   4. Hypercalcemia (high level of calcium in the blood) of malignancy (cancer)

B. **If you have multiple myeloma or bone metastases from a solid tumor, approval also requires:**
   1. Osenvelt will be used to prevent skeletal-related events (such as bone fractures, bone pain requiring radiation [a type of treatment])

C. **If you have giant cell tumor of bone, approval also requires:**
   1. Your tumor is unresectable (unable to remove by surgery) or surgical resection (removal) is likely to result in severe morbidity (illness)

D. **If you have hypercalcemia of malignancy, approval also requires:**
   1. You are refractory (disease did not respond to treatment) to a prior bisphosphonate therapy (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

Effective: 10/01/25

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DENOSUMAB-BMWO-STOBOCLO

Generic	Brand				
DENOSUMAB-BMWO	STOBOCLO				

GUIDELINES FOR USE

Our guideline named **DENOSUMAB-BMWO-STOBOCLO** requires the following rule(s) be met for approval:

You have ONE of the following:
- Postmenopausal osteoporosis (a type of bone condition)
- Osteoporosis (a type of bone condition) in a male patient
- Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)
- Bone loss in men receiving androgen deprivation therapy (type of medication to lower hormone levels, such as Eligard [leuprolide], Zoladex [goserelin]) for non-metastatic prostate cancer (prostate cancer that has not spread to other parts of the body)
- Bone loss in women receiving adjuvant (add-on) aromatase inhibitor therapy (type of breast cancer medication, such as anastrozole, letrozole) for breast cancer

If you have postmenopausal osteoporosis, approval also requires ONE of the following:
- You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
  - You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
  - You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
  - You have had no prior treatment for osteoporosis (a type of bone condition), AND you have a Fracture Risk Assessment Tool (FRAX: a type of test) score of at least 20 percent for any major fracture (a type of complete or partial break in a bone) OR at least 3 percent for a hip fracture
- You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
- You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI: stomach and intestine) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine

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GUIDELINES FOR USE (CONTINUED)

If you are a male with osteoporosis or you have glucocorticoid-induced osteoporosis, approval also requires:
- You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
  - You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
  - You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
- You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])

If you are a man with bone loss who is receiving androgen deprivation therapy for non-metastatic prostate cancer or a woman with bone loss who is receiving adjuvant aromatase inhibitor therapy for breast cancer, approval also requires:
- You are at high risk for fractures (a type of complete or partial break in a bone) (such as history of osteoporotic fracture, history of multiple recent low trauma [injury] fractures, corticosteroid [such as prednisone] use, or use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
- You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])

Effective: 10/01/25

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DENOSUMAB-PROLIA

Generic	Brand				
DENOSUMAB	PROLIA				

GUIDELINES FOR USE

Our guideline named **DENOSUMAB-PROLIA** requires the following rule(s) be met for approval:
You have ONE of the following:
- Postmenopausal osteoporosis (a type of bone condition)
- Osteoporosis (a type of bone condition) in a male patient
- Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)
- Bone loss in men receiving androgen deprivation therapy (type of medication to lower hormone levels, such as Eligard [leuprolide], Zoladex [goserelin]) for non-metastatic prostate cancer (prostate cancer that has not spread to other parts of the body)
- Bone loss in women receiving adjuvant (add-on) aromatase inhibitor therapy (type of breast cancer medication, such as anastrozole, letrozole) for breast cancer

If you have postmenopausal osteoporosis, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Stoboclo (denosumab-bmwo)
- You meet ONE of the following:
  - You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
    - You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
    - You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone analogs [GnRH] [such as Synarel [nafarelin])
    - You have had no prior treatment for osteoporosis (a type of bone condition), AND you have a Fracture Risk Assessment Tool (FRAX: a type of test) score of at least 20 percent for any major fracture (a type of complete or partial break in a bone) OR at least 3 percent for a hip fracture
  - You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
  - You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI: stomach and intestine) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine

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GUIDELINES FOR USE (CONTINUED)

If you are a male with osteoporosis OR you have glucocorticoid-induced osteoporosis, approval also requires:
- You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
  - You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
  - You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
- You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Stoboclo (denosumab-bmwo)

If you are a man with bone loss who is receiving androgen deprivation therapy for non-metastatic prostate cancer or a woman with bone loss who is receiving adjuvant aromatase inhibitor therapy for breast cancer, approval also requires:
- You are at high risk for fracture (a type of complete or partial break in a bone) (such as history of osteoporotic fracture, history of multiple recent low trauma [injury] fractures, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs (such as Synarel [nafarelin])
- You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Stoboclo (denosumab-bmwo)

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DENOSUMAB-XGEVA

Generic	Brand				
DENOSUMAB	XGEVA				

GUIDELINES FOR USE

Our guideline named **DENOSUMAB-XGEVA** requires the following rule(s) be met for approval:
You have ONE of the following:
- Multiple myeloma (a type of blood cancer)
- Bone metastases from a solid tumor (tumor has spread to the bone)
- Giant cell tumor of bone (noncancerous tumor)
- Hypercalcemia (high level of calcium in the blood) of malignancy (cancer)

If you have multiple myeloma or bone metastases from a solid tumor, approval also requires:
- Xgeva will be used to prevent skeletal-related events (such as bone fractures, bone pain requiring radiation [a type of treatment])
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Osenvelt (denosumab-bmwo)

If you have giant cell tumor of bone, approval also requires:
- Your tumor is unresectable (unable to remove by surgery) or surgical resection (removal) is likely to result in severe morbidity (illness)
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Osenvelt (denosumab-bmwo)

If you have hypercalcemia of malignancy, approval also requires:
- You are refractory (disease did not respond to treatment) to a prior bisphosphonate therapy (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Osenvelt (denosumab-bmwo)

Effective: 01/01/26

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DEPEMOKIMAB-ULAA

Generic	Brand				
DEPEMOKIMAB-ULAA	EXDENSUR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEPEMOKIMAB-ULAA (Exdensur)** requires the following rule(s) be met for approval:
You have severe eosinophilic phenotype asthma (a type of inflammatory asthma)
You are 12 years of age or older
Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (relating to lungs/breathing) medicine
You have a blood eosinophil (a type of white blood cell) level of at least 150 cells/mcL within the past 12 months
Exdensur will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
You will NOT use Exdensur concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of inflammatory asthma)
You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)
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INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
- You have experienced at least ONE serious asthma exacerbation (worsening of symptoms) requiring a hospitalization or emergency room visit within the past 12 months
- You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
  - Daytime asthma symptoms more than twice per week
  - Any night waking due to asthma
  - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
  - Any activity limitation due to asthma

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DEPEMOKIMAB-ULAA

RENEWAL CRITERIA

Our guideline named **DEPEMOKIMAB-ULAA (Exdensur)** requires the following rule(s) be met for renewal:

You have severe eosinophilic phenotype asthma (a type of inflammatory asthma)

You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline

You will NOT use Exdensur concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of inflammatory asthma)

You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)

You have shown a clinical response as evidenced by ONE of the following:

- You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Exdensur)
- You have decreased your use of rescue medications (such as albuterol)
- You have an increase in the percent predicted FEV1 (a type of lung test) from pretreatment baseline (before starting Exdensur)
- You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

Effective: 01/12/26

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DESIRUDIN

Generic	Brand			
DESIRUDIN	IPRIVASK			

GUIDELINES FOR USE

Our guideline named **DESIRUDIN (Iprivask)** requires that you are receiving Iprivask for the prevention of deep vein thrombosis (DVT; blood clot in a deep vein, usually in the legs) and you are undergoing elective hip replacement surgery.

Effective: 07/01/20

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DEUCRAVACITINIB

Generic	Brand				
DEUCRAVACITINIB	SOTYKTU				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
- You meet ONE of the following:
  - You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Sotyktu
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp

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DEUCRAVACITINIB

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

RENEWAL CRITERIA

Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

Effective: 03/25/26

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DEURUXOLITINIB

Generic	Brand				
DEURUXOLITINIB PHOSPHATE	LEQSELVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEURUXOLITINIB (Leqselvi)** requires the following rule(s) be met for approval:

A. You have severe alopecia areata (a type of hair loss)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have had at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool), for more than 6 months
E. You will NOT use Leqselvi concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)
F. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Litfulo (ritlecitinib), Olumiant (baricitinib)
G. You have tried or have a contraindication to TWO of the following clinical standard of care medications (from different categories):
    1. Intralesional corticosteroid (such as triamcinolone acetonide)
    2. Topical corticosteroid (such as fluocinolone acetonide, betamethasone dipropionate, clobetasol propionate)
    3. Minoxidil (such as minoxidil 5% solution)
    4. Short contact anthralin
    5. Topical immunotherapy (such as squaric acid dibutyl ester, diphencyprone/diphenylcyclopropenone)
    6. Systemic treatments (such as psoralen plus UV-A [PUVA: a type of light therapy], prednisone, cyclosporine, methotrexate)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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DEURUXOLITINIB

RENEWAL CRITERIA

Our guideline named **DEURUXOLITINIB (Leqselvi)** requires the following rule(s) be met for renewal:

A. You have severe alopecia areata (a type of hair loss)
B. You have experienced improvement while on therapy (such as scalp hair coverage)
C. You will NOT use Leqselvi concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)
D. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Litfulo (ritlecitinib), Olumiant (baricitinib)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 06/10/26

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DEUTETRABENAZINE

Generic	Brand				
DEUTETRABENAZINE	AUSTEDO, AUSTEDO XR				

GUIDELINES FOR USE

Our guideline named **DEUTETRABENAZINE (Austedo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
   2. Moderate to severe tardive dyskinesia (TD: uncontrolled body movements)

B. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or movement disorder specialist
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ingrezza (valbenazine)

C. **If you have moderate to severe tardive dyskinesia, approval also requires:**
   1. You are 18 years of age or older
   2. Your moderate to severe tardive dyskinesia (uncontrolled body movements) has been present for at least 3 months
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), movement disorder specialist, or psychiatrist (a type of mental health doctor)
   4. You have a prior history of using antipsychotic medications (such as aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history
   5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ingrezza (valbenazine)

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DEXMEDETOMIDINE

Generic	Brand				
DEXMEDETOMIDINE HCL	IGALMI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for approval:
- You have acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
- You have tried or have a contraindication to (harmful for you to use) THREE antipsychotics (such as olanzapine, ziprasidone, haloperidol)

RENEWAL CRITERIA

Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for renewal:
- You have acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
- You meet ONE of the following:
  - Your maintenance therapy for the underlying psychiatric (mental) disorder is currently being adjusted/optimized to reduce or eliminate the need for continued PRN (as needed) medications for the treatment of acute agitation
  - Attempts to adjust medications have been exhausted AND your physician (doctor) has determined that chronic PRN (long-term as needed) medications are required for the continued safety of you or your caregivers

Effective: 02/01/26

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DEXTROMETHORPHAN-QUINIDINE

Generic	Brand			
DEXTROMETHORPHAN HBR/QUINIDINE	NUEDEXTA			

GUIDELINES FOR USE

Our guideline named **DEXTROMETHORPHAN-QUINIDINE (Nuedexta)** requires the following rule(s) be met for approval:

A. You have pseudobulbar affect (uncontrollable, inappropriate laughing and/or crying due to a nervous system disorder)

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DIABETIC TEST STRIPS

Generic	Brand			
BLOOD SUGAR DIAGNOSTIC, BLOOD SUGAR DIAGNOSTIC, DISC, BLOOD SUGAR DIAGNOSTIC, DRUM	DIABETIC TEST STRIPS VARIOUS			

GUIDELINES FOR USE

Our guideline named **DIABETIC TEST STRIPS** requires ONE of following rules be met for approval:

A. You have tried ONE preferred blood glucose (diabetic) meter and test strips. The preferred meters and test strips are FreeStyle and Precision by Abbott
B. You require a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment (problems with sight and/or memory and thinking)
C. You require a non-preferred blood glucose test strip because you use another manufacturer's companion insulin pump

Request for non-preferred test strips will not be approved if due to a need for data management software. Please note that data management software is available for the formulary test strip products. Please contact Abbott for data management software and a connection cable for the meter.

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DIAZEPAM

Generic	Brand				
DIAZEPAM	VALTOCO				

GUIDELINES FOR USE

Our guideline named **DIAZEPAM (Valtoco)** requires the following rule(s) be met for approval:

A. You have epilepsy (a type of brain disorder)
B. You are 2 years of age or older
C. Valtoco will be used for the acute (short-term) treatment of intermittent, stereotypic episodes of frequent seizure activity (a condition of increased seizure activity) (seizure clusters, acute repetitive seizures) that are different from your usual seizure pattern

Effective: 07/01/26

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DIAZOXIDE CHOLINE

Generic	Brand				
DIAZOXIDE CHOLINE	VYKAT XR				

GUIDELINES FOR USE

Our guideline named **DIAZOXIDE CHOLINE (Vykat XR)** requires the following rule(s) be met for approval:
You have hyperphagia (extreme hunger)
You are 4 years of age or older
You have genetically confirmed Prader-Willi syndrome (PWS: a type of generic disorder)
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or neurologist (a type of brain and nervous system doctor)

RENEWAL CRITERIA

Our guideline named **DIAZOXIDE CHOLINE (Vykat XR)** requires the following rule(s) be met for renewal:
You have hyperphagia (extreme hunger)
Your hyperphagia is associated with Prader-Willi syndrome (PWS: a type of generic disorder)
You have had clinical improvement

Effective: 05/05/25

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DICHLORPHENAMIDE

Generic	Brand			
DICHLORPHENAMIDE	KEVEYIS, ORMALVI, DICHLORPHENAMIDE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood) or related variants
   2. Primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood) or related variants

B. **If you have primary hyperkalemic periodic paralysis or related variants**, **approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   3. You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

C. **If you have primary hypokalemic periodic paralysis or related variants, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   3. You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

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DICHLORPHENAMIDE

RENEWAL CRITERIA

Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for renewal:

A. You have primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), or related variants
B. You have experienced at least TWO fewer attacks per week from baseline (before you started treatment)

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DIFELIKEFALIN (NSA)

Generic	Brand				
DIFELIKEFALIN ACETATE	KORSUVA				

GUIDELINES FOR USE

Our guideline named **DIFELIKEFALIN (Korsuva)** requires the following rule(s) be met for approval:
You have moderate to severe pruritus (itching) associated with chronic kidney disease
You are 18 years of age or older
You are undergoing hemodialysis (HD: a process of removing excess water and toxins from the blood)

Effective: 07/01/22

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DIGOXIN

Generic	Brand				
DIGOXIN	DIGOXIN, LANOXIN				

GUIDELINES FOR USE

Our guideline named **DIGOXIN (Lanoxin)** requires the following rule(s) be met for approval:
You have ONE of the following:
Heart failure (a type of heart condition)
Chronic atrial fibrillation (a type of heart condition)
If you have chronic atrial fibrillation, approval also requires:
You are 18 years of age or older

Effective: 02/01/26

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DIHYDROERGOTAMINE

Generic	Brand				
DIHYDROERGOTAMINE MESYLATE	TRUDHESA				

GUIDELINES FOR USE

Our guideline named **DIHYDROERGOTAMINE (Trudhesa)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines (a type of headache)
   2. Acute (quick onset) treatment of cluster headache (a type of headache)

B. **If the request is for the acute treatment of migraines, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Trudhesa concurrently (at the same time) with any other dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Ergomar [ergotamine])
   3. You have tried or have a contraindication to (harmful for you to use) ALL of the following preferred medications:
      i. Two triptans (such as Imitrex [sumatriptan], Maxalt [rizatriptan], Relpax [eletriptan])
      ii. One generic dihydroergotamine product (such as dihydroergotamine mesylate 1mg/mL, dihydroergotamine mesylate 0.5mg/spry)
      iii. One calcitonin gene-related peptide (CGRP) inhibitor: Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)

C. **If the request is for the acute treatment of cluster headache, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Trudhesa concurrently (at the same time) with any other dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Ergomar [ergotamine])
   3. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications:
      i. One triptan: Imitrex (sumatriptan injection, sumatriptan intranasal), Zomig (zolmitriptan intranasal)
      ii. One generic dihydroergotamine injectable (e.g., dihydroergotamine mesylate 1mg/mL) or generic dihydroergotamine intranasal (e.g., dihydroergotamine mesylate 0.5mg/spry)

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DIMETHYL FUMARATE

Generic	Brand			
DIMETHYL FUMARATE	TECFIDERA, DIMETHYL FUMARATE			

GUIDELINES FOR USE

Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease goes away and returns), or active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. **If you are requesting brand Tecfidera, approval also requires:**
   1. You have tried generic dimethyl fumarate

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DINUTUXIMAB

Generic	Brand				
DINUTUXIMAB	UNITUXIN				

GUIDELINES FOR USE

Our guideline named **DINUTUXIMAB (Unituxin)** requires the following rule(s) be met for approval:
You have high-risk neuroblastoma (HRNB: a type of cancer)
You are younger than 18 years of age
Unituxin will be used together with a granulocyte-macrophage colony-stimulating factor (GM-CSF: a type of medication used to make more white blood cells), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA) (types of medications used to treat cancer)
You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior first-line multi-agent, multimodal therapy (therapy that includes many medications and ways to treat your condition, such as chemotherapy, surgery, radiation, stem cell transplant)
You have NOT received 5 cycles of Unituxin

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DIROXIMEL FUMARATE

Generic	Brand			
DIROXIMEL FUMARATE	VUMERITY			

GUIDELINES FOR USE

Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease goes away and returns), or active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

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DONANEMAB-AZBT

Generic	Brand				
DONANEMAB-AZBT	KISUNLA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DONANEMAB-AZBT (Kisunla)** requires the following rule(s) be met for approval:

You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

You are 60 years of age or older

You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or psychiatrist (a type of mental health doctor)

You had an amyloid pathology (abnormal buildup of a type of protein) confirmed by positron emission tomography (PET: a type of imaging test) or detected by cerebrospinal fluid (CSF: a type of liquid in the brain and spinal cord)-based testing (such as amyloid-beta 42 [Aβ42], total tau [T-tau], phosphorylated tau [P-tau]) (types of lab tests)

You have a Clinical Dementia Rating (CDR: a tool for evaluating memory loss) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE: a test used to evaluate memory, thinking, and understanding) score of 20 to 28 at baseline (before treatment)

You have Alzheimer's Association Workgroup Clinical Stage 3 (cognitive impairment [decreased ability to process, understand, store and remember information] but mostly maintains independence on activities of daily living [ADL: basic everyday tasks]) or Clinical Stage 4 (cognitive impairment with mild functional impairments on instrumental ADLs but independence in basic ADLs) Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

You have had a baseline brain MRI (magnetic resonance imaging: a type of imaging lab) within 1 year prior to treatment

You had genotype testing (a type of lab test) to determine apolipoprotein E ε4 (ApoE ε4: a type of gene) status prior to initiation of treatment OR you/your caregiver have been counseled on the risk of treatment and have waived genotype testing

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

You are NOT at an increased risk of cerebral bleeding (such as evidence of cerebral microhemorrhages [small amount of bleeding in the brain] or macrohemorrhages [large amount of bleeding in the brain], superficial siderosis [a type of small bleeds in the brain], vasogenic edema [a type of brain swelling], aneurysms [weak bulging spot in the blood vessel] or vascular malformations [abnormal blood vessels], lacunar infarcts [brain stroke] or severe small vessel [damaged small blood vessels in the brain] or white matter disease [damaged nerve fibers in the brain] on screening magnetic resonance imaging [MRI: a type of imaging lab], uncontrolled bleeding disorder, platelet [a type of blood cell] count less than 50,000 or international normalized ratio [a blood test to check how long it takes your blood to clot] greater than 1.5)

You will NOT use Kisunla concurrently (at the same time) with any other anti-amyloid medication (such as Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

RENEWAL CRITERIA

Our guideline named **DONANEMAB-AZBT (Kisunla)** requires the following rule(s) be met for renewal:

You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

If the request is for the first renewal request, renewal also requires:

You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)

You will NOT use Kisunla concurrently (at the same time) with any other anti-amyloid medication (such as Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You do NOT have evidence of amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) on a magnetic resonance imaging (MRI: a type of imaging) scan
- You have a magnetic resonance imaging (MRI: a type of imaging) scan showing amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleed in the brain) and meet ALL of the following:
  - You do NOT have severe symptoms (such as multiple amyloid-related imaging abnormalities [ARIA: abnormal differences in the brain] episodes, macrohemorrhages [large amount of bleeding in the brain], 10 or more microhemorrhages [small amount of bleeding in the brain] since the start of treatment, 3 or more superficial siderosis [a type of small bleeds in the brain] since the start of treatment, severe ARIA, need for anticoagulation [a type of treatment to thin the blood])
  - You have moderate amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) (with or without symptoms) and your doctor has suspended (stopped) infusions until a repeat magnetic resonance imaging (MRI: a type of imaging) scan shows amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) has resolved or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleed in the brain) has stabilized, OR you have asymptomatic (showing no symptoms) mild ARIA with continued MRI monitoring until ARIA-E has resolved or ARIA-H has stabilized

If the request is a subsequent renewal request, renewal also requires:
- You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)
- You will NOT use Kisunla concurrently (at the same time) with any other anti-amyloid medication (such as Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

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DONEPEZIL

Generic	Brand				
DONEPEZIL HCL	ADLARITY				

GUIDELINES FOR USE

Our guideline named **DONEPEZIL (Adlarity)** requires the following rule(s) be met for approval:

A. You have dementia (a type of memory disorder) associated with Alzheimer's disease (a type of brain disorder)
B. You have tried or have a contraindication to (harmful for you to use) TWO generic oral acetylcholinesterase inhibitors (such as donepezil, galantamine)
C. You have tried or have a contraindication to (harmful for you to use) ONE generic acetylcholinesterase inhibitor patch (such as rivastigmine)

Effective: 01/01/25

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DONIDALORSEN

Generic	Brand				
DONIDALORSEN SODIUM	DAWNZERA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DONIDALORSEN (Dawnzera)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Dawnzera will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Dawnzera concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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DONIDALORSEN

RENEWAL CRITERIA

Our guideline named **DONIDALORSEN (Dawnzera)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Dawnzera concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])

Effective: 07/01/26

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DONISLECEL-JUJN (NSA)

Generic	Brand				
DONISLECEL-JUJN	LANTIDRA				

GUIDELINES FOR USE

Our guideline named **DONISLECEL-JUJN (Lantidra)** requires the following rule(s) be met for approval:
You have a diagnosis of type 1 diabetes (a disorder with high blood sugar)
You are 18 years of age or older
You are not able to reach your target hemoglobin A1C (HbA1c: a type of lab test) due to current and repeated episodes of severe hypoglycemia (low blood sugar), despite intensive diabetes management (treatment to control high blood sugar) and education
You have not received a total of 3 doses of Lantidra in your lifetime

Effective: 03/18/24

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DORDAVIPRONE

Generic	Brand				
DORDAVIPRONE HCL	MODEYSO				

GUIDELINES FOR USE

Our guideline named **DORDAVIPRONE (Modeyso)** requires the following rule(s) be met for approval:
You have diffuse midline glioma (a type of brain cancer/tumor)
You are 1 year of age or older
Your tumor has an H3 K27M mutation (abnormal change in a type of gene)
Your disease has progressed (worsened) following prior therapy (such as temozolomide, radiation therapy)

Effective: 09/08/25

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DORNASE ALFA

Generic	Brand				
DORNASE ALFA	PULMOZYME				

GUIDELINES FOR USE

Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:
You have cystic fibrosis (CF: a type of lung disorder)
If you are requesting Pulmozyme (dornase alfa) twice daily dosing, approval also requires:
You have tried and failed Pulmozyme (dornase alfa) once daily dosing

Effective: 03/04/26

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DOSTARLIMAB-GXLY (NSA)

Generic	Brand				
DOSTARLIMAB-GXLY	JEMPERLI				

GUIDELINES FOR USE

Our guideline named **DOSTARLIMAB-GXLY (Jemperli)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Recurrent or advanced endometrial cancer (EC: cancer that starts in the lining of the uterus that has returned or has spread from the original site)
- Primary advanced or recurrent endometrial cancer
- Recurrent or advanced solid tumor

If you have recurrent or advanced endometrial cancer, approval also requires:
- You are 18 years of age or older
- Your cancer has mismatch repair deficient (dMMR: a type of gene mutation) biomarkers, as determined by a Food and Drug Administration (FDA)-approved test
- Your cancer has progressed on or following previous treatment with a platinum-containing regimen (such as carboplatin)
- You are not a candidate for curative surgery (cure the disease) or radiation

If you have primary advanced or recurrent endometrial cancer, approval also requires:
- You are 18 years of age or older
- Jemperli will be used as a single agent OR in combination with carboplatin and paclitaxel

If you have a recurrent or advanced solid tumor, approval also requires:
- You are 18 years of age or older
- Your tumor has mismatch repair deficient (dMMR: a type of gene mutation) biomarkers, as determined by a Food and Drug Administration (FDA)-approved test
- Your tumor has progressed on or following prior treatment (such as carboplatin, oxaliplatin, irinotecan)
- You have no satisfactory alternative treatment options

Effective: 08/19/24

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DOXECITINE-DOXRIBTIMINE

Generic	Brand				
DOXECITINE/DOXRIBTIMINE	KYGEVVI				

GUIDELINES FOR USE

Our guideline named **DOXECITINE-DOXRIBTIMINE (Kygevvi)** requires the following rule(s) be met for approval:

A. You have thymidine kinase 2 deficiency (TK2d: a type of genetic disorder)
B. Your age at symptom onset for thymidine kinase 2 deficiency (TK2d: a type of genetic disorder) is 12 years or younger

Effective: 07/01/26

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DOXYCYCLINE

Generic	Brand				
DOXYCYCLINE MONOHYDRATE	ORACEA, DOXYCYCLINE IR-DR				

GUIDELINES FOR USE

Our guideline named **DOXYCYCLINE (Oracea, Doxycycline IR-DR)** requires the following rule(s) be met for approval:
You have rosacea (a type of skin condition)
You are 18 years of age or older
You have inflammatory lesions (papules and pustules: small bumps on the skin) associated with rosacea
You have tried or have a contraindication to (harmful for you to use) ONE generic oral minocycline or doxycycline monohydrate/hyclate

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DROXIDOPA

Generic	Brand				
DROXIDOPA	NORTHERA, DROXIDOPA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for approval:
You have neurogenic orthostatic hypotension (nOH: a type of low blood pressure)
Your condition is caused by primary autonomic failure (Parkinson's disease [PD: a type of movement disorder], multiple system atrophy [a type of nervous system disorder], or pure autonomic failure [a type of nervous system disorder]), dopamine beta-hydroxylase deficiency (type of genetic disorder), or non-diabetic autonomic neuropathy (a type of nerve disorder)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or cardiologist (a type of heart doctor)
You have tried or have a contraindication to (harmful for you to use) midodrine or fludrocortisone
Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
You have experienced a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
You have persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'

RENEWAL CRITERIA

Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:
You have neurogenic orthostatic hypotension (nOH: a type of low blood pressure)
You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
You have experienced an increase in systolic blood pressure from baseline of at least 10 mmHg upon standing from a supine (lying face up) position

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DUPILUMAB

Generic	Brand				
DUPILUMAB	DUPIXENT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)
   6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
   7. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]
   8. Bullous pemphigoid (BP: a type of skin condition)
   9. Allergic fungal rhinosinusitis (AFRS: inflammation of nasal and sinus ways due to an allergic reaction to fungi)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 6 months of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Rinvoq [upadacitinib]) and are switching to Dupixent
      b. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
      c. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)

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INITIAL CRITERIA (CONTINUED)

5. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast]), topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

C. **If you have moderate to severe asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You meet ONE of the following:
      a. You have an eosinophilic phenotype asthma (a type of inflammatory asthma) and meet all of the following:
         i. You have a pre-treatment blood eosinophil level (a type of lab test) of 150 to 1500 cells/mcL
         ii. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
      b. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
   4. Dupixent will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

D. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
   4. You have inadequately controlled disease
   5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
   6. Dupixent will be used as add-on maintenance treatment (in conjunction [together] with maintenance intranasal steroids [a type of medication used in the nose])
   7. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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INITIAL CRITERIA (CONTINUED)

E. **If you have eosinophilic esophagitis, approval also requires:**
   1. You are 1 year of age or older
   2. You weigh at least 15 kilograms (33 pounds)
   3. Therapy is prescribed by or in consultation with a gastroenterologist (a type of doctor who treats digestive conditions), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) dietary therapy
   5. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)
   6. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

F. **If you have prurigo nodularis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
   3. You have multiple pruriginous lesions (wounds)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine
   5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

G. **If you have chronic obstructive pulmonary disease, approval also requires:**
   1. You are 18 years of age or older
   2. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   4. You have a blood eosinophil level (a type of lab test) of at least 300 cells/mcL
   5. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
   6. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

H. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
   4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), 4-times the maximally labeled dose of a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
   5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

I. **If you have bullous pemphigoid, approval also requires:**
   1. You are 18 years of age or older

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INITIAL CRITERIA (CONTINUED)

J. **If you have allergic fungal rhinosinusitis, approval also requires:**
   1. You are 6 years of age or older
   2. You have a history of sino-nasal surgery (a type of surgery)
   3. You have inadequately controlled disease after endoscopic sinus surgery (a type of surgery)
   4. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray, fluticasone nasal spray, beclomethasone nasal spray)

RENEWAL CRITERIA

NOTE: For the diagnosis of bullous pemphigoid (BP), please refer to the Initial Criteria section.

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)
   6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
   7. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]
   8. Allergic fungal rhinosinusitis (AFRS: inflammation of nasal and sinus ways due to an allergic reaction to fungi)

B. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have shown improvement while on Dupixent
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

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RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe asthma, renewal also requires:**
   1. You meet ONE of the following:
      a. You have an eosinophilic phenotype asthma (a type of inflammatory asthma), AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
      b. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
   2. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Dupixent)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

D. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

(Renewal criteria continued on next page)

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

E. **If you have eosinophilic esophagitis, renewal also requires**:
   1. You have shown improvement while on Dupixent (such as symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less [a type of test that evaluates disease status])
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

F. **If you have prurigo nodularis, renewal also requires:**
   1. You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

G. **If you have chronic obstructive pulmonary disease, renewal also requires:**
   1. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
   2. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD
   4. You have shown a clinical response as evidenced by ONE of the following:
      a. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
      b. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)
      c. You have had an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Dupixent)

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

H. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:**
   1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

I. **If you have allergic fungal rhinosinusitis, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)

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DURVALUMAB

Generic	Brand				
DURVALUMAB	IMFINZI				

GUIDELINES FOR USE

Our guideline named **DURVALUMAB (Imfinzi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-small cell lung cancer (NSCLC: a type of lung cancer)
   2. Small cell lung cancer (SCLC: a type of lung cancer)
   3. Locally advanced or metastatic biliary tract cancer (a type of biliary tract cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   4. Unresectable hepatocellular carcinoma (a type of liver cancer that cannot be completely removed by surgery)
   5. Primary advanced or recurrent endometrial cancer (a type of uterus cancer that has spread or has returned after treatment)
   6. High-risk non-muscle invasive bladder cancer (NMIBC: bladder cancer that has not spread to the muscles)
   7. Muscle invasive bladder cancer (MIBC: bladder cancer that has spread to the muscles)
   8. Resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) (a type of digestive system cancer that can be removed by surgery)

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GUIDELINES FOR USE (CONTINUED)

B. **If you have non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is resectable (can be removed by surgery) (node positive [has spread to the lymph nodes] or tumors are at least 4 cm); you have no known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements; and Imfinzi will be used in combination with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant treatment (additional treatment) after surgery and previous use in combination with platinum-containing chemotherapy
      b. Your cancer is Stage III and unresectable (cannot be completely removed by surgery); and your disease has NOT progressed (worsened) after using concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT: concurrent chemoradiotherapy)
      c. Your cancer is metastatic (cancer that has spread to other parts of the body); you do NOT have sensitizing epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (a type of abnormal gene); and Imfinzi will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

C. **If you have small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have limited-stage cancer (LS: cancer that is contained in a single area on one side of the chest) AND your disease has NOT progressed (worsened) following concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT: concurrent chemoradiotherapy)
      b. You have extensive-stage cancer (ES: cancer that has spread widely throughout the lungs or other parts of the body) and Imfinzi will be used in combination with etoposide, AND either carboplatin or cisplatin

D. **If you have locally advanced or metastatic biliary tract cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Imfinzi will be used in combination with gemcitabine and cisplatin

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

E. **If you have unresectable hepatocellular carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Imfinzi will be used in combination with Imjudo (tremelimumab-actl)

F. **If you have primary advanced or recurrent endometrial cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is mismatch repair deficient (dMMR: a type of gene mutation [abnormal change]), as determined by a Food and Drug Administration (FDA)-approved test
   3. Imfinzi will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

G. **If you have high-risk non-muscle invasive bladder cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment) naive (have not previously used BCG)
   3. You will use Imfinzi in combination with Bacillus Calmette-Guérin (BCG)

H. **If you have muscle invasive bladder cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Imfinzi will be used in combination with gemcitabine and cisplatin as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant treatment (additional treatment) following radical cystectomy (bladder removal surgery) and previous use in combination with gemcitabine and cisplatin

I. **If you have resectable gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Imfinzi will be used in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant (given before main treatment) and adjuvant (add-on) treatment, OR as a single-agent after prior use in combination with FLOT

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DUVELISIB

Generic	Brand			
DUVELISIB	COPIKTRA			

GUIDELINES FOR USE

Our guideline named **DUVELISIB (Copiktra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Relapsed or refractory chronic lymphocytic leukemia (CLL: a type of blood cancer that has returned after treatment or did not fully respond to treatment)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
B. You are 18 years of age or older
C. You have received at least two prior therapies for chronic lymphocytic leukemia or small lymphocytic lymphoma

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ECALLANTIDE

Generic	Brand				
ECALLANTIDE	KALBITOR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Kalbitor will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. Kalbitor will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis (severe, possible life-threatening allergic reaction) and/or angioedema (a type of swelling)
F. You will NOT use Kalbitor concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Firazyr [icatibant])
G. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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ECALLANTIDE

RENEWAL CRITERIA

Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use Kalbitor concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Firazyr [icatibant])

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ECULIZUMAB

Generic	Brand				
ECULIZUMAB	SOLIRIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

Soliris (eculizumab) is NOT being used for the treatment of hemolytic uremic syndrome related to Shiga toxin E. coli (a bacteria)

If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
- You have tried and failed (as shown by hemoglobin [Hgb: a type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
- You will NOT use Soliris concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

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ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have generalized myasthenia gravis, approval also requires:

- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
- You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
- You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
- You will NOT use Soliris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
  - You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)
- If you are 18 years of age or older, approval also requires:
  - You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

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ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have neuromyelitis optica spectrum disorder, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
- You have a positive test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ultomiris (ravulizumab-cwvz)
- You will NOT use Soliris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])
- You have at least ONE of the following core clinical characteristics:
  - Optic neuritis (a type of brain disorder)
  - Acute myelitis (a type of brain disorder)
  - Area postrema syndrome (a type of brain disorder)
  - Acute brainstem syndrome (a type of brain disorder)
  - Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

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ECULIZUMAB

RENEWAL CRITERIA

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
- You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before treatment)
- You will NOT use Soliris concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

If you have generalized myasthenia gravis, renewal also requires:
- You have experienced a clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
- You will NOT use Soliris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

If you have neuromyelitis optica spectrum disorder, renewal also requires:
- You have experienced a reduction in relapse frequency compared to baseline (before treatment)
- You will NOT use Soliris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

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ECULIZUMAB-AAGH

Generic	Brand				
ECULIZUMAB-AAGH	EPYSQLI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ECULIZUMAB-AAGH (Epysqli)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

Epysqli (eculizumab-aagh) is NOT being used for the treatment of hemolytic uremic syndrome related to Shiga toxin E. coli (a bacteria)

If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
- You have tried and failed (as shown by hemoglobin [Hgb: a type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
- You will NOT use Epysqli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

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INITIAL CRITERIA (CONTINUED)

If you have generalized myasthenia gravis, approval also requires:

- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
- You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
- You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
- You will NOT use Epysqli concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
  - You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)
- If you are 18 years of age or older, approval also requires:
  - You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

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ECULIZUMAB-AAGH

INITIAL CRITERIA (CONTINUED)

If you have neuromyelitis optica spectrum disorder, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
- You have a positive test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ultomiris (ravulizumab-cwvz)
- You will NOT use Epysqli concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])
- You have at least ONE of the following core clinical characteristics:
  - Optic neuritis (a type of brain disorder)
  - Acute myelitis (a type of brain disorder)
  - Area postrema syndrome (a type of brain disorder)
  - Acute brainstem syndrome (a type of brain disorder)
  - Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

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ECULIZUMAB-AAGH

RENEWAL CRITERIA

Our guideline named **ECULIZUMAB-AAGH (Epysqli)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
- You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before treatment)
- You will NOT use Epysqli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

If you have generalized myasthenia gravis, renewal also requires:
- You have experienced a clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
- You will NOT use Epysqli concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

If you have neuromyelitis optica spectrum disorder, renewal also requires:
- You have experienced a reduction in relapse frequency compared to baseline (before treatment)
- You will NOT use Epysqli concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

Effective: 02/01/26

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EDARAVONE (NSA)

Generic	Brand			
EDARAVONE	RADICAVA, EDARAVONE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for approval:
You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
You have had the disease (from onset of symptoms) for 2 years or less
You have normal respiratory (breathing) function (such as Forced Vital Capacity [FVC: a type of lung test] of at least 80 percent)
You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)
You have tried riluzole OR are currently taking riluzole

RENEWAL CRITERIA

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for renewal:
You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
You do not require invasive ventilation (inserting a breathing tube into the throat)
You have improved baseline functional ability as measured by Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R: a tool for evaluating functional status) OR you have maintained a score of 2 or greater in all 12 items of ALSFRS-R

Effective: 08/01/24

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EDARAVONE ORAL

Generic	Brand				
EDARAVONE	RADICAVA ORS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or an amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition) specialist at an ALS Specialty Center or Care Clinic
C. You have had amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition) (from onset of symptoms) for 2 years or less
D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of at least 80%
E. You have tried the clinical standard of care medication riluzole OR are currently taking riluzole
F. You have mild to moderate amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition) with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)

RENEWAL CRITERIA

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. You do not require invasive ventilation (inserting a breathing tube into the throat)
C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status)

Effective: 07/01/26

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EFBEMALENOGRASTIM ALFA-VUXW

Generic	Brand				
EFBEMALENOGRASTIM ALFA-VUXW	RYZNEUTA				

GUIDELINES FOR USE

Our guideline named **EFBEMALENOGRASTIM ALFA-VUXW (Ryzneuta)** requires the following rule(s) be met for approval:

You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)

You are 18 years of age or older

You have a non-myeloid malignancy (cancer not affecting bone marrow)

Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

Effective: 06/01/25

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EFGARTIGIMOD

Generic	Brand				
EFGARTIGIMOD ALFA-FCAB	VYVGART				
EFGARTIGIMOD-HYALURONIDAS-QVFC	VYVGART HYTRULO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EFGARTIGIMOD (Vyvgart, Vyvgart Hytrulo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   2. Chronic inflammatory demyelinating polyneuropathy (CIDP: a type of nerve disorder)

B. **If you have generalized myasthenia gravis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   3. You have Myasthenia Gravis Foundation of America class II, III, or IV (type of severity of disease)
   4. You have tried or have a contraindication to (harmful for you to use) the following clinical standard of care medications: one generic corticosteroid (such as prednisone) AND one generic non-steroidal immunosuppressive therapy (such as azathioprine, cyclophosphamide, methotrexate)
   5. You will NOT use the requested medication concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Imaavy [nipocalimab-aahu]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

C. **If you have chronic inflammatory demyelinating polyneuropathy, approval also requires:**
   1. You are 18 years of age or older
   2. The request is for Vyvgart Hytrulo

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EFGARTIGIMOD

RENEWAL CRITERIA

NOTE: For the diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP), please refer to the Initial Criteria section.

Our guideline named **EFGARTIGIMOD (Vyvgart, Vyvgart Hytrulo)** requires the following rule(s) be met for renewal:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You have had clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
C. You will NOT use the requested medication concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Imaavy [nipocalimab-aahu]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

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EFLAPEGRASTIM-XNST

Generic	Brand				
EFLAPEGRASTIM-XNST	ROLVEDON				

GUIDELINES FOR USE

Our guideline named **EFLAPEGRASTIM-XNST (Rolvedon)** requires the following rule(s) be met for approval:

A. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
B. You are 18 years of age or older
C. You have a non-myeloid malignancy (cancer not affecting bone marrow)
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

Effective: 01/01/25

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EFLORNITHINE

Generic	Brand				
EFLORNITHINE HCL	IWILFIN				

GUIDELINES FOR USE

Our guideline named **EFLORNITHINE (Iwilfin)** requires the following rule(s) be met for approval:
You have high-risk neuroblastoma (HRNB: a type of rare cancer)
You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior therapy, including anti-GD2 immunotherapy (such as Unituxin [dinutuximab])

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ELACESTRANT

Generic	Brand				
ELACESTRANT HCL	ORSERDU				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELACESTRANT (Orserdu)** requires the following rule(s) be met for approval:

A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
C. You have had disease progression (worsening) following at least ONE line of endocrine therapy (a type of hormone therapy such as anastrozole, letrozole)
D. Therapy is prescribed by or in consultation with an oncology specialist (a type of cancer doctor)
E. You will NOT use Orserdu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Veppanu [vepdegestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

RENEWAL CRITERIA

Our guideline named **ELACESTRANT (Orserdu)** requires the following rule(s) be met for renewal:

A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
C. You have experienced clinical benefit while on therapy as shown by a partial (cancer has shrunk but did not go away) or complete response (cancer went away completely) OR stable disease (disease has stopped growing or spreading)
D. You will NOT use Orserdu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Veppanu [vepdegestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

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ELAFIBRANOR

Generic	Brand				
ELAFIBRANOR	IQIRVO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for approval:
- You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
  - You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
  - You have antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or you have other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210 if AMA is negative
  - You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)
- You do NOT have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)
- You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])
- You meet ONE of the following:
  - Iqirvo will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (UDCA: ursodeoxycholic acid)
  - Iqirvo will be used in combination (together) with ursodiol (UDCA: ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (UDCA: ursodeoxycholic acid) monotherapy (one drug treatment)

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ELAFIBRANOR

RENEWAL CRITERIA

Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for renewal:
You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Iqirvo
You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

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ELAGOLIX

Generic	Brand				
ELAGOLIX SODIUM	ORILISSA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:

A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
E. You have normal liver function, or mild to moderate hepatic (liver) impairment (Child-Pugh Class A or B: a tool for evaluating severity of liver damage)
F. Requests for Orilissa 200 mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
G. Requests will not be approved if you have previously received ONE of the following:
    1. A 6-month course of Orilissa 200 mg twice daily
    2. A 6-month course of Orilissa 150 mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
    3. A 24-month course of Orilissa 150 mg once daily and you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

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ELAGOLIX

RENEWAL CRITERIA

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:

A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
B. You have improvement of pain related to endometriosis while on therapy
C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
E. Requests will not be approved if you have previously received ONE of the following:
    1. A 6-month course of Orilissa 200 mg twice daily
    2. A 6-month course of Orilissa 150 mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
    3. A 24-month course of Orilissa 150 mg once daily and you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Effective: 08/07/26

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

Generic	Brand				
ELAGOLIX/ESTRADIOL /NORETHINDRONE	ORIAHNN				

GUIDELINES FOR USE

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You are 18 years of age or older
C. You are a premenopausal (before menopause) woman
D. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
E. You will NOT use Oriahnn concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Myfembree [relugolix/estradiol/norethindrone], Lupron Depot [leuprolide])
F. You have not received a total of 24 months cumulative treatment with Oriahnn

RENEWAL CRITERIA

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for renewal:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You have had improvement of heavy menstrual bleeding on therapy
C. You will NOT use Oriahnn concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Myfembree [relugolix/estradiol/norethindrone], Lupron Depot [leuprolide])
D. You have not received a total of 24 months cumulative treatment with Oriahnn

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ELAPEGADEMASE-LVLR

Generic	Brand			
ELAPEGADEMASE-LVLR	REVCOVI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. You have adenosine deaminase severe combined immune deficiency (ADA-SCID: an inherited disorder that damages the immune system) as shown by ONE of the following:
   1. You have a confirmatory genetic test
   2. You have suggestive laboratory findings (such as elevated deoxyadenosine nucleotide levels, lymphopenia [low levels of a type of white blood cell]) AND you have hallmark signs/symptoms (such as recurrent infections, failure to thrive, persistent diarrhea)
B. Therapy is prescribed by or in consultation with an immunologist (a type of immune system doctor), hematologist-oncologist (a type of blood-cancer doctor), or physician specializing in inherited metabolic disorders
C. You meet ONE of the following:
   1. You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow)
   2. Revcovi will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

RENEWAL CRITERIA

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:

A. You have adenosine deaminase severe combined immune deficiency (ADA-SCID: an inherited disorder that damages the immune system)
B. You have a trough plasma adenosine deaminase (ADA) activity of at least 30 mmol/hr/L AND trough deoxyadenosine nucleotide (dAXP) levels less than 0.02 mmol/L
C. You have shown improvement in or maintenance of immune function from baseline (such as a decrease in the number and severity of infections)
D. You have NOT received successful hematopoietic cell transplantation (HCT: blood cell transplant from bone marrow) or gene therapy

Effective: 07/01/24

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ELAMIPRETIDE

Generic	Brand				
ELAMIPRETIDE HCL	FORZINITY				

GUIDELINES FOR USE

Our guideline named **ELAMIPRETIDE (Forzinity)** requires the following rule(s) be met for approval:
You have Barth syndrome (a rare genetic condition)
You weigh at least 30 kilograms (66 pounds)

Effective: 10/20/25

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ELBASVIR/GRAZOPREVIR

Generic	Brand			
ELBASVIR/GRAZOPREVIR	ZEPATIER			

GUIDELINES FOR USE

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 12 years of age or older OR weigh at least 30 kilograms (66 pounds)
C. You have genotype 1 or 4 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Zepatier concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as phenytoin, carbamazepine, rifampin, efavirenz [such as Atripla, Sustiva], atazanavir [such as Evotaz, Reyataz], darunavir [such as Prezcobix, Prezista], lopinavir, saquinavir, Aptivus [tipranavir], cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir [such as Stribild, Genvoya], atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, St. John's wort)
H. You will NOT use Zepatier concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
I. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa, Harvoni

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

J. **If you are treatment-naive (no prior treatment), approval also requires ONE of the following:**
   1. You have genotype 1a infection AND you do not have baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein)
   2. You have genotype 1b infection
   3. You have genotype 4 infection
   4. You received a kidney transplant (replaced your kidney) AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)
   5. You have genotype 1a infection, with baseline NS5A polymorphisms, AND Zepatier will be used with ribavirin

K. **If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:**
   1. You have genotype 1a infection, without baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein), AND were previously treated with peginterferon/ribavirin
   2. You have genotype 1b infection AND were previously treated with peginterferon/ribavirin
   3. You have genotype 1 infection, were previously treated with a peginterferon/ribavirin/protease inhibitor triple regimen, AND Zepatier will be used with ribavirin
   4. You have genotype 1a infection with baseline NS5A polymorphisms, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   5. You have genotype 4 infection, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   6. You received a kidney transplant (replaced your kidney), were previously treated with a non-direct acting antiviral (such as interferon), AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)

L. Zepatier will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Effective: 07/22/24

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ELEXACAFTOR-TEZACAFTOR-IVACAFTOR

Generic	Brand				
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR	TRIKAFTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You have at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (a type of gene) that is either responsive to Trikafta based on clinical or in vitro data (testing outside of the body in a tube) or that results in the production of CFTR protein

RENEWAL CRITERIA

Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You have experienced an improvement in your clinical status
C. You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

Effective: 05/09/26

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ELINZANETANT

Generic	Brand				
ELINZANETANT	LYNKUET				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELINZANETANT (Lynkuet)** requires the following rule(s) be met for approval:

You have moderate to severe menopausal vasomotor symptoms (VMS: symptoms related to menopause)

You experience at least 7 hot flashes per day

You will NOT use Lynkuet concurrently (at the same time) with another hormonal (such as Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (such as Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) medication for vasomotor symptoms (symptoms related to menopause)

You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: hormonal therapy (such as estradiol transdermal patch [such as Minivelle, Climara], oral conjugated estrogens [such as Premarin], micronized progesterone [such as Prometrium])

RENEWAL CRITERIA

Our guideline named **ELINZANETANT (Lynkuet)** requires the following rule(s) be met for renewal:

You have moderate to severe menopausal vasomotor symptoms (VMS: symptoms related to menopause)

You have a continued need for vasomotor symptoms (symptoms related to menopause) treatment (persistently symptomatic with hot flashes)

You have had a reduction in vasomotor symptoms (symptoms related to menopause) frequency or severity due to Lynkuet treatment

You will NOT use Lynkuet concurrently (at the same time) with another hormonal (such as Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (such as Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) medication for vasomotor symptoms (symptoms related to menopause)

Effective: 12/01/25

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ELOSULFASE ALFA (NSA)

Generic	Brand			
ELOSULFASE ALFA	VIMIZIM			

GUIDELINES FOR USE

Our guideline named **ELOSULFASE ALFA (Vimizim)** requires you have Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome - rare metabolic condition that mainly affects the skeleton).

Effective: 07/01/20

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ELOTUZUMAB (NSA)

Generic	Brand			
ELOTUZUMAB	EMPLICITI			

GUIDELINES FOR USE

Our guideline named **ELOTUZUMAB (Empliciti)** requires the following rule(s) be met for approval:
You have multiple myeloma (plasma cell cancer)
You are 18 years of age or older
You meet ONE of the following criteria:
- Empliciti is used in combination with lenalidomide and dexamethasone if you have received one to three prior therapies such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation
- Empliciti is used in combination with pomalidomide and dexamethasone if you have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as bortezomib, carfilzomib, ixazomib)

Effective: 04/10/21

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ELRANATAMAB-BCMM (NSA)

Generic	Brand				
ELRANATAMAB-BCMM	ELREXFIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELRANATAMAB-BCMM (Elrexfio)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
B. You are 18 years of age or older
C. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

RENEWAL CRITERIA

Our guideline named **ELRANATAMAB-BCMM (Elrexfio)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
B. You have received at least 24 weeks of treatment with Elrexfio
C. You have responded to treatment with Elrexfio (a partial response [PR] or better), and have maintained this response for at least 2 months

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ELTROMBOPAG - ALVAIZ

Generic	Brand				
ELTROMBOPAG CHOLINE	ALVAIZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
   3. Severe aplastic anemia (a type of blood disorder)

B. **If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 6 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
   3. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])
   4. You meet ONE of the following:
      a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
      b. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND a prior bleeding event

C. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. You are 18 years of age or older
   2. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of medication to treat liver infection) or limits your ability to maintain interferon-based therapy

D. **If you have severe aplastic anemia, approval also requires:**
   1. You are 18 years of age or older
   2. You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)

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ELTROMBOPAG - ALVAIZ

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rules be met for renewal:

A. You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Alvaiz) OR a decrease in bleeding events
C. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])

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ELTROMBOPAG - PROMACTA

Generic	Brand				
ELTROMBOPAG OLAMINE	PROMACTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Persistent or chronic immune (idiopathic) thrombocytopenia (a type of blood disorder)
   2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
   3. Severe aplastic anemia (a type of blood disorder)

B. **If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 1 year of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
   3. You will NOT use Promacta concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag])
   4. You meet ONE of the following:
      a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
      b. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND a prior bleeding event

C. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of medication to treat liver infection) or limits your ability to maintain interferon-based therapy

D. **If you have severe aplastic anemia, approval also requires:**
   1. You meet ONE of the following:
      a. You are 2 years of age or older AND Promacta will be used in combination (together) with standard immunosuppressive therapy (treatment that lowers the activity of the body's immune system) as first-line treatment (used for initial treatment)
      b. You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)

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ELTROMBOPAG - PROMACTA

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rules be met for renewal:

A. You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Promacta) OR a decrease in bleeding events
C. You will NOT use Promacta concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag])

Effective: 07/22/26

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EMAPALUMAB-LZSG

Generic	Brand				
EMAPALUMAB-LZSG	GAMIFANT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Primary (familial) hemophagocytic lymphohistiocytosis (HLH: a type of genetic immune disorder)
- Hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) (a type of immune disorder)

If you have primary hemophagocytic lymphohistiocytosis, approval also requires:

- Therapy is prescribed by or in consultation with an immunologist (doctor who specializes in immune disorders), hematologist (a type of blood doctor), or oncologist (a type of cancer doctor)
- Gamifant will be used at the same time with dexamethasone
- You have refractory, recurrent, or progressive disease (disease does not respond to treatment, returns, or is getting worse) OR you have tried or had an intolerance (side effect) to conventional hemophagocytic lymphohistiocytosis therapy (chemotherapy, steroids, immunotherapy)
- Your diagnosis is confirmed by ONE of the following:
  - You have undergone a genetic test identifying HLH-associated gene mutation (such as PRF1 [type of gene], UNC13D [type of gene])
  - You have at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly (enlarged spleen); cytopenias (low number of a type of blood cell affecting at least 2 of 3 cell lineages); hypertriglyceridemia (high level of triglycerides, a type of fat in blood) and/or hypofibrinogenemia (low level of fibrinogen, a type of protein in the blood); hemophagocytosis (destruction of certain types of cells) in bone marrow or spleen or lymph nodes, and no evidence of malignancy (cancer); low or absent natural killer-cell (white blood cells) activity; ferritin level (a type of lab test) of at least 500 mcg/L; soluble CD25 level (a type of lab test) of at least 2,400 U/mL

(Initial criteria continued on next page)

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EMAPALUMAB-LZSG

INITIAL CRITERIA (CONTINUED)

If you have hemophagocytic lymphohistiocytosis/macrophage activation syndrome, approval also requires:

You have known or suspected Still's disease (an autoinflammatory disease) or systemic juvenile idiopathic arthritis (sJIA: a type of joint condition)

You had an inadequate response (treatment did not work) or intolerance (side effect) to glucocorticoids OR you have a recurrent (disease has returned) macrophage activation syndrome (MAS: a type of immune disorder)

RENEWAL CRITERIA

NOTE: For the diagnosis of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS), please refer to the Initial Criteria section.

Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for renewal:

You have primary (familial) hemophagocytic lymphohistiocytosis (HLH: a type of genetic immune disorder)

You have not received a successful hematopoietic stem cell transplantation (bone marrow transplant)

You have demonstrated improved immune system response from baseline as shown by any of the following: your fever has gone away, decreased splenomegaly (spleen size has gotten smaller), improvement in central nervous system symptoms (such as altered mental status), improved complete blood count, increased fibrinogen levels, or reduced D-dimer, ferritin, or soluble CD25 (types of proteins) levels

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Effective: 08/11/25

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EMICIZUMAB-KXWH

Generic	Brand				
EMICIZUMAB-KXWH	HEMLIBRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:

A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
C. Hemlibra will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
D. You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])
E. **If you have hemophilia A with factor VIII inhibitors (a type of protein), approval also requires:**
    1. You have a history of a high titer (concentration) of factor VIII inhibitor, defined as at least 5 Bethesda units per milliliter
F. **If you have hemophilia A without factor VIII inhibitors (a type of protein), approval also requires ONE of the following:**
    1. You have moderate to severe hemophilia A, defined as less than 5 percent factor VIII activity compared to normal
    2. You have mild hemophilia A, defined as 5 percent - 40 percent factor VIII activity compared to normal, and meet ONE of the following:
        a. You have experienced severe, traumatic, or spontaneous (sudden) bleeding episode(s) (may occur in joint or muscle)
        b. You have experienced a life-threatening bleed (such as intracranial hemorrhage [ICH: a type of bleeding in the head])
        c. It is difficult to access your veins which prevents or delays you in receiving regular clotting factor infusions

RENEWAL CRITERIA

Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:

A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
B. You have shown a clinical benefit compared to baseline (before starting Hemlibra)
C. You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])

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ENALAPRIL

Generic	Brand				
ENALAPRIL MALEATE	EPANED, ENALAPRIL MALEATE				

GUIDELINES FOR USE

Our guideline named **ENALAPRIL (Epaned)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hypertension (high blood pressure)
- Symptomatic heart failure (a type of heart condition)
- Asymptomatic left ventricular dysfunction (a type of heart condition)

If you have hypertension, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow enalapril tablets

If you have symptomatic heart failure, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow enalapril tablets

If you have asymptomatic left ventricular dysfunction, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow enalapril tablets

Effective: 01/01/26

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ENASIDENIB

Generic	Brand				
ENASIDENIB MESYLATE	IDHIFA				

GUIDELINES FOR USE

Our guideline named **ENASIDENIB (Idhifa)** requires the following rule(s) be met for approval:
You have relapsed or refractory acute myeloid leukemia (AML: a type of blood and bone marrow cancer that has returned after or is resistant to treatment)
You are 18 years of age or older
You are isocitrate dehydrogenase-2 (a type of enzyme) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

Effective: 02/01/26

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ENCORAFENIB

Generic	Brand				
ENCORAFENIB	BRAFTOVI				

GUIDELINES FOR USE

Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
- Metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

If you have unresectable or metastatic melanoma, approval also requires:
- You have a BRAF V600E or V600K mutation (abnormal change in types of genes), as detected by a Food and Drug Administration (FDA)-approved test
- Braftovi will be used in combination with Mektovi (binimetinib)

If you have metastatic colorectal cancer, approval also requires:
- You are 18 years of age or older
- You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- You meet ONE of the following:
  - Braftovi will be used in combination with Erbitux (cetuximab) and fluorouracil-based chemotherapy (such as mFOLFOX6 [fluorouracil, leucovorin and oxaliplatin], FOLFIRI [fluorouracil, leucovorin, and irinotecan])
  - Braftovi will be used in combination with Erbitux (cetuximab), and you have previously received treatment (such as irinotecan)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- Braftovi will be used in combination with Mektovi (binimetinib)

Effective: 03/11/26

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ENFORTUMAB

Generic	Brand				
ENFORTUMAB VEDOTIN-EJFV	PADCEV				

GUIDELINES FOR USE

Our guideline named **ENFORTUMAB (Padcev)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic urothelial cancer (mUC: type of urinary system cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
   2. Bladder cancer

B. **If you have locally advanced or metastatic urothelial cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Padcev will be used as a single agent, and you meet ONE of the following:
         i. You have previously received a medication that works against a type of protein called programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1), AND you have previously received a platinum (such as cisplatin, carboplatin)-containing chemotherapy (type of cancer medication)
         ii. You are not eligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy
      b. Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)

C. **If you have bladder cancer, approval also requires**
   1. You are 18 years of age or older
   2. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall)
   3. Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph), as neoadjuvant treatment (given before main treatment), and then continued after cystectomy (bladder removal surgery) as adjuvant treatment (additional treatment)

Effective: 07/29/26

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ENSARTINIB

Generic	Brand				
ENSARTINIB HYDROCHLORIDE	ENSACOVE				

GUIDELINES FOR USE

Our guideline named **ENSARTINIB (Ensacove)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue/lymph nodes or other parts of the body)
B. You are 18 years of age or older
C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive
D. You have NOT previously received an ALK-inhibitor (such as Xalkori [crizotinib], Alecensa [alectinib])

Effective: 07/01/25

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ENSIFENTRINE

Generic	Brand				
ENSIFENTRINE	OHTUVAYRE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for approval:

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You are 18 years of age or older
C. Ohtuvayre will be used as maintenance treatment (taken on a regular basis)
D. Therapy is prescribed by or in consultation with a pulmonologist (a type of lung/breathing doctor)
E. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater

RENEWAL CRITERIA

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for renewal:

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater
C. You have shown a clinical response as evidenced by ONE of the following:
    1. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Ohtuvayre)
    2. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum (mucus) production, etc.)
    3. You have an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Ohtuvayre)

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ENTRECTINIB

Generic	Brand				
ENTRECTINIB	ROZLYTREK				

GUIDELINES FOR USE

Our guideline named **ENTRECTINIB (Rozlytrek)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
- Solid tumor (an abnormal mass)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your tumor is ROS1-positive (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test

If you have a solid tumor, approval also requires:
- You are 1 month of age or older
- The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (an abnormal change in a type of gene that does not have any known resistance), as detected by a Food and Drug Administration (FDA)-approved test
- Your tumor is metastatic (has spread to other parts of the body), or surgical resection (removal) is likely to result in severe morbidity (disease)
- You have progressed (gotten worse) after treatment or there are no satisfactory alternative treatments

If the request is for Rozlytrek 50 mg pellets, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) Rozlytrek capsules that are used to make an oral suspension
- You have difficulty or are not able to swallow capsules

Effective: 02/01/26

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ENZALUTAMIDE

Generic	Brand				
ENZALUTAMIDE	XTANDI				

GUIDELINES FOR USE

Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Castration-resistant prostate cancer (CRPC: prostate cancer that does not respond to hormone therapy)
- Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
- Non-metastatic castration-sensitive prostate cancer (nmCSPC: prostate cancer that has not spread to other parts of the body and responds to hormone therapy)

If you have castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer, approval also requires ONE of the following:
- You have received a bilateral orchiectomy (surgical removal of both testicles)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If you have non-metastatic castration-sensitive prostate cancer, approval also requires:
- You are at high risk for metastasis (prostate specific antigen [PSA] level has doubled over 9 months or less)
- You meet ONE of the following:
  - You have received a bilateral orchiectomy (surgical removal of both testicles)
  - You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
  - Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Effective: 11/10/25

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EPCORITAMAB-BYSP

Generic	Brand				
EPCORITAMAB-BYSP	EPKINLY				

GUIDELINES FOR USE

Our guideline named **EPCORITAMAB-BYSP (Epkinly)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of blood cancer that has returned or is not responding to treatment), including DLBCL arising from indolent (slow growing) lymphoma (a type of blood cancer), OR high-grade B-cell lymphoma (a type of blood cancer)
- Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or is not responding to treatment)

If you have diffuse large B-cell lymphoma or high-grade B-cell lymphoma, approval also requires:

- You are 18 years of age or older
- You previously received at least two lines of systemic therapy (treatment that travels throughout the body) (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])

If you have follicular lymphoma, approval also requires:

- You are 18 years of age or older
- You meet ONE of the following:
  - Epkinly will be used in combination with lenalidomide (Revlimid) and rituximab
  - Epkinly will be used as monotherapy (one medication treatment) after receiving at least two lines of systemic therapy (treatment that travels throughout the body) (such as Gazyva [obinutuzumab], bendamustine, rituximab, Revlimid [lenalidomide])

Effective: 12/15/25

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EPLONTERSEN

Generic	Brand				
EPLONTERSEN SODIUM	WAINUA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (*transthyretin*) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

RENEWAL CRITERIA

Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for renewal:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You have not progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
C. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

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EPOETIN ALFA

Generic	Brand				
EPOETIN ALFA	EPOGEN, PROCRIT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
- Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
- Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
- Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
- You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

If you have anemia due to chronic kidney disease, approval also requires:

- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 10g/dL
- You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:

- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level
- You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

(Initial criteria continued on next page)

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 10g/dL
- You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 10g/dL
- You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
- You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
- You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
- Your hemoglobin level (a type of blood test) is less than 13g/dL
- You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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EPOETIN ALFA

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
- Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
- Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
- Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

If you have anemia due to chronic kidney disease, renewal also requires:

- You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
- If you are an adult (you are 18 years of age or older), renewal also requires ONE of the following:
  - Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
  - Your hemoglobin level (a type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
  - Your hemoglobin level (a type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
  - Your hemoglobin level (a type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

(Renewal criteria continued on next page)

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

If you are a pediatric patient (you are less than 18 years of age), renewal also requires ONE of the following:
Your hemoglobin level (a type of blood test) is less than 10g/dL
Your hemoglobin level (a type of blood test) has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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EPOETIN ALFA-EPBX

Generic	Brand				
EPOETIN ALFA-EPBX	RETACRIT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
- Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
- Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
- Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
- You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

If you have anemia due to chronic kidney disease, approval also requires:

- Your hemoglobin level (a type of blood test) is less than 10g/dL
- You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:

- Your hemoglobin level (a type of blood test) is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level
- You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

(Initial criteria continued on next page)

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
- Your hemoglobin level (a type of blood test) is less than 10g/dL
- You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
- Your hemoglobin level (a type of blood test) is less than 10g/dL
- You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
- You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
- Your hemoglobin level (a type of blood test) is less than 13g/dL
- You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
- Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
- Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
- Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

If you have anemia due to chronic kidney disease, renewal also requires:

- You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
- If you are an adult (you are 18 years of age or older), renewal also requires ONE of the following:
  - Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
  - Your hemoglobin level (a type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
  - Your hemoglobin level (a type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
  - Your hemoglobin level (a type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

(Renewal criteria continued on next page)

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

If you are a pediatric patient (you are less than 18 years of age), renewal also requires ONE of the following:
Your hemoglobin level (a type of blood test) is less than 10g/dL
Your hemoglobin level (a type of blood test) has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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EPOPROSTENOL IV (NSA)

Generic	Brand				
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN, EPOPROSTENOL SODIUM				
EPOPROSTENOL SODIUM	VELETRI, EPOPROSTENOL SODIUM				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPOPROSTENOL IV (Flolan, Veletri)** requires the following rule(s) be met for approval:

You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)

Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

Our guideline named **EPOPROSTENOL IV (Flolan, Veletri)** requires the following rule(s) be met for renewal:

You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Effective: 07/01/24

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EPTINEZUMAB-JJMR

Generic	Brand				
EPTINEZUMAB-JJMR	VYEPTI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Episodic migraines (a type of headache)
- Chronic migraines (a type of headache)

If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Vyepti is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention
- You have tried TWO of the following preferred medications: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), Nurtec ODT (rimegepant), Qulipta (atogepant), Ajovy (fremanezumab-vfrm)

If you have chronic migraines (at least 15 headache days per month), approval also requires:
- You are 18 years of age or older
- Vyepti is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention
- You have tried TWO of the following preferred medications: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), Nurtec ODT (rimegepant), Qulipta (atogepant), Ajovy (fremanezumab-vfrm)

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EPTINEZUMAB-JJMR

RENEWAL CRITERIA

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:

The request is for the preventive treatment of migraines (a type of headache)

You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention

You meet ONE of the following:

- You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Vyepti therapy
- You have experienced a decrease in migraine (a type of headache) severity with Vyepti therapy
- You have experienced a decrease in migraine (a type of headache) duration with Vyepti therapy

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Effective: 04/01/26

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ERDAFITINIB

Generic	Brand				
ERDAFITINIB	BALVERSA				

GUIDELINES FOR USE

Our guideline named **ERDAFITINIB (Balversa)** requires the following rule(s) be met for approval:

You have locally advanced or metastatic urothelial carcinoma (a type of bladder cancer that has spread to nearby tissue or other parts of the body)

You are 18 years of age or older

You have a susceptible (can be treated with the drug) fibroblast growth factor receptor 3 (FGFR3: a type of protein) genetic alteration (mutation) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test

You have disease progression (condition has worsened) on or after at least one line of prior systemic therapy (treatment that targets the entire body, such as cisplatin, Keytruda [pembrolizumab])

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ERENUMAB-AOOE

Generic	Brand				
ERENUMAB-AOOE	AIMOVIG				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Episodic migraines (a type of headache)
- Chronic migraines (a type of headache)

If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Aimovig is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

If you have chronic migraines (15 or more headache days per month), approval also requires:
- You are 18 years of age or older
- Aimovig is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

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ERENUMAB-AOOE

RENEWAL CRITERIA

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:
The request is for the preventive treatment of migraines (a type of headache)
You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention
You meet ONE of the following:
- You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Aimovig therapy
- You have experienced a decrease in migraine (a type of headache) severity with Aimovig therapy
- You have experienced a decrease in migraine (a type of headache) duration with Aimovig therapy

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ERGOTAMINE

Generic	Brand				
ERGOTAMINE TARTRATE	ERGOMAR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERGOTAMINE (Ergomar)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines (a type of headache)
   2. Treatment of cluster headache (a type of headache)

B. **If the request is for the acute treatment of migraines, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Ergomar concurrently (at the same time) with any other dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])
   3. You have tried or have a contraindication to (harmful for you to use) ALL of the following preferred medications:
      a. Two triptans (such as Imitrex [sumatriptan], Maxalt [rizatriptan], Relpax [eletriptan])
      b. One generic dihydroergotamine product (such as dihydroergotamine mesylate 1mg/mL, dihydroergotamine mesylate 0.5mg/spry)
      c. One calcitonin gene-related peptide (CGRP) inhibitor: Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)

C. **If the request is for the treatment of cluster headache, approval also requires:**
   1. You are 18 years of age or older
   2. Your symptoms were NOT adequately managed with abortive therapies (such as Imitrex [sumatriptan], Zomig [zolmitriptan], oxygen)
   3. You will NOT use Ergomar concurrently (at the same time) with any additional dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication for preventive treatment: verapamil

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ERGOTAMINE

RENEWAL CRITERIA

NOTE: For the request for the acute treatment of migraines, please refer to the Initial Criteria section.

Our guideline named **ERGOTAMINE (Ergomar)** requires the following rule(s) be met for renewal:

A. The request is for the treatment of cluster headache (a type of headache)
B. You had improvement in cluster headache frequency as compared to baseline (before treatment)
C. You will NOT use Ergomar concurrently (at the same time) with any additional dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])

Effective: 07/01/26

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ERIBULIN (NSA)

Generic	Brand			
ERIBULIN MESYLATE	HALAVEN, ERIBULIN MESYLATE			

GUIDELINES FOR USE

Our guideline named **ERIBULIN (Halaven)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic breast cancer (cancer that has spread to other parts of the body)
- Unresectable or metastatic liposarcoma (cancer that begins in the fat cells and cannot be completely removed with surgery or that has spread to other parts of the body)

If you have metastatic breast cancer, approval also requires:
- You have tried at least TWO chemotherapeutic regimens (drugs used to treat cancer) in the adjuvant (add on treatment) or metastatic setting, which include one medication from EACH of the following drug classes:
  - An anthracycline (a type of cancer treatment such as daunorubicin [Cerubidine], doxorubicin [Adriamycin], epirubicin [Ellence])
  - A taxane (a type of cancer treatment such as docetaxel [Taxotere], paclitaxel [Taxol, Abraxane])

If you have unresectable or metastatic liposarcoma, approval also requires:
- You have tried an anthracycline-containing regimen (a type of cancer treatment such as daunorubicin [Cerubidine], doxorubicin [Adriamycin], epirubicin [Ellence])

Effective: 05/06/24

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ERLOTINIB

Generic	Brand				
ERLOTINIB HCL	TARCEVA, ERLOTINIB HCL				

GUIDELINES FOR USE

Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
- Locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)

If you have metastatic non-small cell lung cancer, approval also requires:
- Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that make up a gene) as detected by an FDA (Food and Drug Administration)-approved test
- You will NOT use Tarceva (erlotinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Gilotrif [afatinib], Tagrisso [osimertinib], Iressa [gefitinib], Vizimpro [dacomitinib])

If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:
- The requested medication will be used in combination with gemcitabine

Effective: 02/01/26

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ESKETAMINE

Generic	Brand				
ESKETAMINE HCL	SPRAVATO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
   2. Major depressive disorder (MDD: a type of mental illness)

B. **If you have treatment-resistant depression, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor) or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider (a doctor that is authorized to prescribe the requested medication)
   3. You have non-psychotic, unipolar depression (you have depression that does not involve hallucinations or delusions)
   4. You do NOT have active substance (drug) abuse

C. **If you have major depressive disorder, approval also requires:**
   1. You are 18 years of age or older
   2. Spravato will be used in combination with an oral antidepressant (such as Zoloft [sertraline], Cymbalta [duloxetine])
   3. You have acute (short-term) suicidal ideation or behavior (thoughts of killing yourself)
   4. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor) or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider (a doctor that is authorized to prescribe the requested medication)
   5. You have non-psychotic, unipolar depression (you have depression that does not involve hallucinations or delusions)
   6. You do NOT have active substance (drug) abuse

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ESKETAMINE

RENEWAL CRITERIA

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
   2. Major depressive disorder (MDD: a type of mental illness)

B. You have demonstrated clinical benefit (improvement in depression) compared to baseline (before treatment)

Effective: 07/27/26

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ETANERCEPT

Generic	Brand			
ETANERCEPT	ENBREL			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

E. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as naproxen, ibuprofen, meloxicam)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Enbrel
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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ETANERCEPT

RENEWAL CRITERIA

Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Ankylosing spondylitis (AS: a type of joint condition)
   5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

(Renewal criteria continued on next page)

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

E. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

F. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

Effective: 06/24/26

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ETELCALCETIDE (NSA)

Generic	Brand			
ETELCALCETIDE	PARSABIV			

GUIDELINES FOR USE

Our guideline named **ETELCALCETIDE (Parsabiv)** requires the following rule(s) be met for approval:
You have secondary hyperparathyroidism (too much parathyroid hormone due to low blood calcium levels)
You are 18 years of age or older
You have chronic kidney disease
You are on hemodialysis (a way of removing toxins from your blood)
You are NOT taking another calcimimetic agent (a drug that acts like calcium in the body such as cinacalcet)

Effective: 07/01/20

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ETEPLIRSEN

Generic	Brand				
ETEPLIRSEN	EXONDYS-51				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ETEPLIRSEN (Exondys 51)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You have a confirmed mutation (abnormal change in a type of gene) in the DMD gene that will respond to exon 51 skipping therapy (a type of therapy to treat DMD)
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of DMD at a DMD treatment center
D. You are ambulatory (able to walk)
E. You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

RENEWAL CRITERIA

Our guideline named **ETEPLIRSEN (Exondys 51)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

Effective: 02/24/25

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ETHACRYNIC ACID

Generic	Brand				
ETHACRYNIC ACID	EDECRIN, ETHACRYNIC ACID				

GUIDELINES FOR USE

Our guideline named **ETHACRYNIC ACID (Edecrin)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), cirrhosis (liver damage), or renal disease (including nephrotic syndrome [a type of kidney disorder])
   2. Ascites (accumulation of fluid in the abdominal cavity) due to malignancy (cancer), idiopathic (unknown cause) edema, or lymphedema (swelling in an arm or leg due to build-up of lymph fluid)

B. You have tried or have a contraindication to (harmful for you to use) TWO preferred generic loop diuretics (such as furosemide, bumetanide, torsemide)

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ETRASIMOD

Generic	Brand				
ETRASIMOD ARGININE	VELSIPITY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for approval:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
D. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Skyrizi (risankizumab-rzaa)
    3. Tremfya (guselkumab)
    4. Omvoh (mirikizumab-mrkz)
    5. Adalimumab-ryvk/adalimumab-aaty
    6. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
    7. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ETRASIMOD

RENEWAL CRITERIA

Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for renewal:

B. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
C. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   2. Skyrizi (risankizumab-rzaa)
   3. Tremfya (guselkumab)
   4. Omvoh (mirikizumab-mrkz)
   5. Adalimumab-ryvk/adalimumab-aaty
   6. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
   7. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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EVEROLIMUS-AFINITOR DISPERZ

Generic	Brand				
EVEROLIMUS	AFINITOR DISPERZ, EVEROLIMUS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EVEROLIMUS-AFINITOR DISPERZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
   2. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

B. **If you have tuberous sclerosis complex-associated subependymal giant cell astrocytoma, approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

C. **If you have tuberous sclerosis complex-associated partial-onset seizures, approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication will be used as adjunctive (add-on) treatment
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: an anti-seizure medication (such as vigabatrin, carbamazepine, levetiracetam, oxcarbazepine, valproic acid derivatives, clobazam, topiramate, lamotrigine)
   5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Epidiolex (cannabidiol)

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EVEROLIMUS-AFINITOR DISPERZ

RENEWAL CRITERIA

NOTE: For the diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma, please refer to the Initial Criteria section.

Our guideline named **EVEROLIMUS-AFINITOR DISPERZ** requires the following rule(s) be met for renewal:

A. You have tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

Effective: 05/20/26

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EVEROLIMUS-AFINITOR

Generic	Brand				
EVEROLIMUS	AFINITOR, TORPENZ, YULITHIRA, EVEROLIMUS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EVEROLIMUS-AFINITOR (Afinitor, Torpenz, Yulithira)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced breast cancer
   2. Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
   3. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   4. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated renal angiomyolipoma (type of kidney tumor)
   5. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
   6. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

B. **If you have advanced breast cancer, approval also requires:**
   1. You are a postmenopausal (after menopause) woman
   2. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   3. The requested medication will be used in combination with exemestane
   4. You have failed or have a contraindication to (harmful for you to use) treatment with Femara (letrozole) or Arimidex (anastrozole)

C. **If you have progressive neuroendocrine tumors with unresectable, locally advanced or metastatic disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
      b. You have well-differentiated, non-functional neuroendocrine tumors (NET: a rare type of tumor) of gastrointestinal (GI: relating to the digestive system) or lung origin

(Initial criteria continued on next page)

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EVEROLIMUS-AFINITOR

INITIAL CRITERIA (CONTINUED)

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
E. **If you have tuberous sclerosis complex-associated renal angiomyolipoma, approval also requires:**
   1. You are 18 years of age or older
   2. You do NOT require immediate surgery
F. **If you have tuberous sclerosis complex-associated subependymal giant cell astrocytoma, approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely removed with surgery)
G. **If you have tuberous sclerosis complex-associated partial-onset seizures, approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication will be used as adjunctive (add-on) treatment
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: an anti-seizure medication (such as vigabatrin, carbamazepine, levetiracetam, oxcarbazepine, valproic acid derivatives, clobazam, topiramate, lamotrigine)
   5. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: Epidiolex (cannabidiol)

RENEWAL CRITERIA

NOTE: For the diagnoses of advanced breast cancer, progressive neuroendocrine tumors with unresectable, locally advanced or metastatic disease, advanced renal cell carcinoma, tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, and tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma, please refer to the Initial Criteria section.

Our guideline named **EVEROLIMUS-AFINITOR (Afinitor, Torpenz, Yulithira)** requires the following rule(s) be met for renewal:

A. You have tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

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EVINACUMAB-DGNB

Generic	Brand				
EVINACUMAB-DGNB	EVKEEZA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for approval:
You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
You are 1 year of age or older
Evkeeza will be used as an adjunct (add-on) to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), endocrinologist (a type of hormone doctor), or lipidologist (a type of cholesterol doctor)
You have tried or have a contraindication to (harmful for you to use) Zetia (ezetimibe)
You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Repatha (evolocumab)
- You do NOT have functional LDL (low-density lipoprotein) receptors

If you are statin tolerant, approval also requires:
- You meet ONE of the following:
  - You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
  - You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), but you are currently taking a maximally tolerated dose of any statin
- You will continue statin treatment in combination with Evkeeza

(Initial criteria continued on the next page)

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EVINACUMAB-DGNB

INITIAL CRITERIA (CONTINUED)

If you are statin intolerant, approval also requires ONE of the following:

- You have an absolute contraindication to (harmful for you to use) statin therapy (such as active decompensated liver disease [symptoms related to liver damage], nursing [breastfeeding] female, pregnancy or plans to become pregnant, hypersensitivity [allergic] reaction)
- You have complete statin intolerance (defined by severe and intolerable adverse effects) that have occurred with trials of at least TWO separate statins, AND the adverse effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation at least 10 times the upper limit of normal, liver function test elevation at least 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group.

RENEWAL CRITERIA

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for renewal:
You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
Your low-density lipoprotein-cholesterol (LDL-C) level has decreased while on Evkeeza
You meet ONE of the following:

- You have continued to take a maximally tolerated dose of ANY statin along with Evkeeza
- You have an absolute contraindication to (harmful for you to use) statin therapy
- You have complete statin intolerance (severe and intolerable adverse effects)

Effective: 01/01/26

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

Generic	Brand				
FAM-TRASTUZUMAB DERUXTECAN-NXKI	ENHERTU				

GUIDELINES FOR USE

Our guideline named **FAM-TRASTUZUMAB DERUXTECAN-NXKI (Enhertu)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic breast cancer (a type of cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Early breast cancer
   3. Unresectable or metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that cannot be removed by surgery or has spread to other parts of the body)
   4. Locally advanced or metastatic gastric OR gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
   5. Unresectable or metastatic solid tumors (a type of abnormal mass that cannot be removed by surgery or has spread to other parts of the body)

B. **If you have unresectable or metastatic breast cancer, approval also requires ONE of the following:**
   1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive), and you meet ONE of the following:
      a. You have received a prior anti-HER2-based regimen (such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emtansine]) in the metastatic setting (cancer has spread to other parts of the body)
      b. You have received a prior anti-HER2-based regimen (such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emtansine]) in the neoadjuvant (given before main treatment) or adjuvant (additional treatment) setting AND the disease returned during or within 6 months of completing therapy
      c. You will use Enhertu in combination with pertuzumab (Perjeta), when your cancer is determined by a Food and Drug Administration (FDA)-authorized test
   2. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining), as determined by a Food and Drug Administration (FDA)-authorized test, AND your disease has progressed (worsened) while on at least one endocrine therapy (such as letrozole, anastrozole, tamoxifen) in the metastatic setting (cancer has spread to other parts of the body)

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

3. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-), as determined by a Food and Drug Administration (FDA)-authorized test, and you meet ONE of the following:
   a. You have received a prior chemotherapy (a type of cancer treatment) in the metastatic setting (cancer has spread to other parts of the body)
   b. You have developed disease recurrence (disease has returned) during or within 6 months of completing adjuvant (additional) chemotherapy

C. **If you have early breast cancer, approval also requires ONE of the following:**
   1. Your cancer is early Stage II or III; your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive), as determined by a Food and Drug Administration (FDA)-authorized test; AND Enhertu will be used as a neoadjuvant treatment (given before main treatment) and followed by a taxane (such as paclitaxel), trastuzumab, and pertuzumab (THP)
   2. Your cancer is in early stage; your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive); Enhertu will be used as adjuvant treatment (additional treatment); and you have residual invasive disease (remaining disease that has spread) following neoadjuvant (given before main treatment) trastuzumab and taxane-based treatment

D. **If you have unresectable or metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumors have activating HER2 (ERBB2) mutations (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-authorized test
   3. You have received a prior systemic therapy (treatment that targets the entire body)

E. **If you have locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or IHC 2+/ISH positive)
   3. You have received a prior trastuzumab-based (type of medication) regimen

F. **If you have unresectable or metastatic solid tumors, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+)
   3. You have received previous systemic treatment (therapy that targets the entire body) and have no other satisfactory treatment options

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FARICIMAB-SVOA

Generic	Brand				
FARICIMAB-SVOA	VABYSMO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FARICIMAB-SVOA (Vabysmo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
   2. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
   3. Macular edema following retinal vein occlusion (RVO: a type of eye condition)

B. **If you have neovascular (wet) age-related macular degeneration, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

C. **If you have diabetic macular edema, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

D. **If you have macular edema following retinal vein occlusion, approval also requires:**
   1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

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FARICIMAB-SVOA

RENEWAL CRITERIA

Our guideline named **FARICIMAB-SVOA (Vabysmo)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
   2. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
   3. Macular edema following retinal vein occlusion (RVO: a type of eye condition)

B. **If you have neovascular (wet) age-related macular degeneration, renewal also requires:**
   1. You have maintained or improved visual acuity (vison clarity or sharpness)
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

C. **If you have diabetic macular edema, renewal also requires:**
   1. You have maintained or improved visual acuity (vison clarity or sharpness)
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

D. **If you have macular edema following retinal vein occlusion, renewal also requires:**
   1. You have maintained or improved visual acuity (vison clarity or sharpness)
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

Effective: 05/09/26

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FECAL MICROBIOTA CAPSULE

Generic	Brand				
FECAL MICROBIO SPORE, LIVE-BRPK	VOWST				

GUIDELINES FOR USE

Our guideline named **FECAL MICROBIOTA CAPSULE (Vowst)** requires the following rule(s) be met for approval:

Vowst will be used for the prevention of recurrent *Clostridioides difficile (C. difficile)* infection (CDI: a bacterial infection)

You are 18 years of age or older

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or infectious disease specialist (a doctor who specializes in the treatment of infections)

If you have NOT previously been treated with Vowst, approval also requires:

You have completed antibiotic (such as vancomycin [Vancocin], fidaxomicin [Dificid]) treatment for recurrent *Clostridioides difficile* infection (CDI: a bacterial infection) (defined as at least 3 CDI episodes)

If you have previously been treated with Vowst, approval also requires:

You had treatment failure, defined as the presence of *Clostridioides difficile* infection (CDI: a bacterial infection) diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile* (a type of bacteria)

You have NOT previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

Effective: 01/01/26

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FECAL MICROBIOTA SUSPENSION

Generic	Brand				
FECAL MICROBIOTA, LIVE-JSLM	REBYOTA				

GUIDELINES FOR USE

Our guideline named **FECAL MICROBIOTA SUSPENSION (Rebyota)** requires the following rule(s) be met for approval:

Rebyota will be used for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)

You are 18 years of age or older

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or infectious disease specialist (a doctor who specializes in the treatment of infections)

If you have NOT previously been treated with Rebyota, approval also requires:

You have completed antibiotic (such as vancomycin [Vancocin]) treatment for recurrent *Clostridioides difficile* infection (CDI: a bacterial infection) (defined as at least 3 CDI episodes) at least 24 hours prior

If you have previously been treated with Rebyota, approval also requires:

You had treatment failure, defined as the presence of *Clostridioides difficile* infection (CDI: a bacterial infection) diarrhea within 8 weeks of the first dose of Rebyota, AND a positive stool test for *C. difficile* (a type of bacteria)

You have NOT previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

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FEDRATINIB

Generic	Brand				
FEDRATINIB DIHYDROCHLORIDE	INREBIC				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for approval:
- You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) Jakafi (ruxolitinib)

RENEWAL CRITERIA

Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:
- You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
- You have shown symptom improvement by meeting ONE of the following:
  - You have a spleen volume reduction of at least 35% from baseline (before treatment)
  - You have at least a 50% reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
  - You have at least a 50% reduction in palpable (can be felt by external examination) spleen length

Effective: 01/01/26

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FENFLURAMINE

Generic	Brand				
FENFLURAMINE HCL	FINTEPLA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
You have seizures associated with ONE of the following:
- Dravet syndrome (a rare type of seizure)
- Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)

If you have Dravet syndrome, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following: valproic acid derivative, clobazam

If you have Lennox-Gastaut syndrome, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have tried or have a contraindication to (harmful for you to use) valproic acid or derivatives
- You have tried or have a contraindication to (harmful for you to use) TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

RENEWAL CRITERIA

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for renewal:
You have seizures associated with ONE of the following:
- Dravet syndrome (a rare type of seizure)
- Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)

Effective: 10/01/25

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FENTANYL TRANSDERMAL PATCH

Generic	Brand			
FENTANYL	DURAGESIC, FENTANYL			

GUIDELINES FOR USE

Our guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain-relieving dose) of another opioid
B. The requested medication is not prescribed on an 'as needed' basis
C. Requests for every 48 hours dosing requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

Effective: 10/14/24

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FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand				
FENTANYL CITRATE	ACTIQ, FENTANYL CITRATE				

GUIDELINES FOR USE

Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq)** requires the following rule(s) be met for approval:

You have cancer-related pain

You are on a maintenance dose of a controlled-release pain medication (such as MS Contin [morphine extended-release], Oxycontin [oxycodone extended-release], Duragesic [fentanyl patch])

You have difficulty swallowing tablets or capsules, OR you have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], oxycodone/acetaminophen, hydrocodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)

You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic fentanyl citrate lozenge (which also requires a prior authorization)

Effective: 03/04/26

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FILGRASTIM

Generic	Brand				
FILGRASTIM	NEUPOGEN				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM (Neupogen)** requires the following rule(s) be met for approval:

You meet ONE of the following:

- You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting bone marrow)
- You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
- You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells), and you have a non-myeloid malignancy (cancer not affecting the bone marrow)
- You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
- You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
- You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Effective: 02/01/26

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FILGRASTIM-AAFI

Generic	Brand				
FILGRASTIM-AAFI	NIVESTYM				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM-AAFI (Nivestym)** requires the following rule(s) be met for approval:

You meet ONE of the following:

- You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting bone marrow)
- You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
- You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells), and you have a non-myeloid malignancy (cancer not affecting bone marrow)
- You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
- You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles or due to unknown cause)
- You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

Effective: 02/01/26

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FILGRASTIM-AYOW

Generic	Brand				
FILGRASTIM-AYOW	RELEUKO				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM-AYOW (Releuko)** requires the following rule(s) be met for approval:

You meet ONE of the following:

- You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting the bone marrow)
- You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
- You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells), and you have a non-myeloid malignancy (cancer not affecting the bone marrow)
- You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
- You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles, or due to unknown cause)
- You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Effective: 02/01/26

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FILGRASTIM-SNDZ

Generic	Brand				
FILGRASTIM-SNDZ	ZARXIO				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM-SNDZ (Zarxio)** requires the following rule(s) be met for approval:

You meet ONE of the following:

- You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting bone marrow)
- You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
- You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells), and you have a non-myeloid malignancy (cancer not affecting bone marrow)
- You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
- You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
- You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Effective: 02/01/26

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FILGRASTIM-TXID

Generic	Brand				
FILGRASTIM-TXID	NYPOZI				

GUIDELINES FOR USE

Our guideline named **FILGRASTIM-TXID (Nypozi)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have non-myeloid malignancy (cancer not affecting the bone marrow)
   2. You have undergone or are undergoing induction or consolidation chemotherapy (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
   3. You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood-forming cells), and you have non-myeloid malignancy (cancer not affecting the bone marrow)
   4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown causes)
   6. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]: an illness that happens after whole body radiation)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

Effective: 05/20/26

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FINGOLIMOD

Generic	Brand			
FINGOLIMOD	GILENYA, FINGOLIMOD			

GUIDELINES FOR USE

Our guideline named **FINGOLIMOD (Gilenya)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 10 years of age or older
C. You do NOT have ANY of the following contraindications to (harmful for you to use) Gilenya:
    1. A recent (within the past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke (a type of brain damage), transient ischemic attack (a type of stroke), decompensated heart failure (a type of heart condition) requiring hospitalization, or Class III/IV heart failure (a type of heart condition)
    2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)
    3. A baseline QTc interval of 500 msec or above (a measure of the speed of electrical conduction in the heart)
    4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Effective: 06/01/24

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FINGOLIMOD LAURYL SULFATE

Generic	Brand				
FINGOLIMOD LAURYL SULFATE	TASCENSO ODT				

GUIDELINES FOR USE

Our guideline named **FINGOLIMOD LAURYL SULFATE (Tascenso ODT)** requires the following rule(s) be met for approval:

- You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
- You are 10 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow oral fingolimod oral capsules
- You do NOT have any of the following contraindications to (harmful for you to use) Tascenso ODT:
  - A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
  - A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)
  - A baseline QTc interval of at least 500 msec (a measure of the speed of electrical conduction in the heart)
  - Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

If you are 18 years of age or older, approval also requires:

- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

Effective: 01/01/26

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FITUSIRAN

Generic	Brand				
FITUSIRAN SODIUM	QFITLIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FITUSIRAN (Qfitlia)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hemophilia A (a type of bleeding disorder)
- Hemophilia B (a type of bleeding disorder)

If you have hemophilia A, approval also requires:
- You are 12 years of age or older
- Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

If you have hemophilia B, approval also requires:
- You are 12 years of age or older
- Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

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FITUSIRAN

RENEWAL CRITERIA

Our guideline named **FITUSIRAN (Qfitlia)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Hemophilia A (a type of bleeding disorder)
- Hemophilia B (a type of bleeding disorder)

If you have hemophilia A, renewal also requires:
- You have shown a clinical benefit compared to baseline (before starting Qfitlia)
- You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

If you have hemophilia B, renewal also requires:
- You have shown a clinical benefit compared to baseline (before starting Qfitlia)
- You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

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FLIBANSERIN

Generic	Brand				
FLIBANSERIN	ADDYI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **FLIBANSERIN (Addyi)** requires the following rule(s) be met for approval:
You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by ALL of the following criteria:
- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty

You are a female
You are 18 to 64 years of age
You previously had a trial of bupropion, unless there is a medical reason why you cannot (contraindication)
You are not currently using Vyleesi (bremelanotide)

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FLIBANSERIN

RENEWAL CRITERIA

Our guideline for **FLIBANSERIN (Addyi)** requires the following rule(s) be met for renewal:

You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:

- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty

You are a female

You are not currently using Vyleesi (bremelanotide)

You have demonstrated continued improvement in symptoms of hypoactive sexual desire disorder/female sexual interest and arousal disorder (such as increased sexual desire, lessened distress)

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FLUOROURACIL CREAM

Generic	Brand				
FLUOROURACIL	CARAC, FLUOROURACIL				
FLUOROURACIL	FLUOROPLEX				

**** Please use the criteria for the specific drug requested ****

GUIDELINE FOR USE

CARAC

Our guideline named **FLUOROURACIL CREAM (Carac)** requires the following rule(s) be met for approval:

A. You have actinic or solar keratosis (AK: a type of skin condition)
B. You have actinic or solar keratosis on the face or anterior (front) scalp
C. You have tried TWO preferred generic topical (applied to skin) medications for AK (such as fluorouracil 5%, imiquimod, diclofenac 3%)

FLUOROPLEX

Our guideline named **FLUOROURACIL CREAM (Fluoroplex)** requires the following rule(s) be met for approval:

A. You have actinic or solar keratosis (AK: a type of skin condition)
B. You have tried TWO preferred generic topical (applied to skin) medications for AK (such as fluorouracil, imiquimod, diclofenac 3%)

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FOSCARBIDOPA-FOSLEVODOPA

Generic	Brand				
FOSCARBIDOPA/ FOSLEVODOPA	VYALEV				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for approval:

A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. Vyalev will be used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. Your disease is responsive to treatment with levodopa
E. You are currently being treated with at least 400mg of levodopa per day
F. Your motor symptoms are currently uncontrolled (defined as an average 'off' time of at least 2.5 hours per day over 3 consecutive days, with a minimum of 2 hours each day)
G. You meet ONE of the following:
    1. You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
    2. You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

RENEWAL CRITERIA

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for renewal:

A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. You have experienced improvement in motor symptoms with the use of Vyalev

Effective: 04/01/25

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FOSDENOPTERIN

Generic	Brand				
FOSDENOPTERIN HYDROBROMIDE	NULIBRY				

GUIDELINES FOR USE

Our guideline named **FOSDENOPTERIN (Nulibry)** requires the following rule(s) be met for approval:
You have molybdenum cofactor deficiency (MoCD) Type A (a type of rare genetic condition)

Effective: 02/01/26

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FOSTAMATINIB

Generic	Brand				
FOSTAMATINIB DISODIUM	TAVALISSE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:
You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
You have a platelet (a type of blood cell) count of less than 30 x 10^9/L, OR you have a platelet count of less than 50 x 10^9/L AND had a prior bleeding event
You will NOT use Tavalisse concurrently (at the same time) with a Bruton's tyrosine kinase (BTK) inhibitor (such as Wayrilz [rilzabrutinib]) for the treatment of chronic immune thrombocytopenia

RENEWAL CRITERIA

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:
You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Tavalisse) OR a decrease in bleeding events
You will NOT use Tavalisse concurrently (at the same time) with a Bruton's tyrosine kinase (BTK) inhibitor (such as Wayrilz [rilzabrutinib]) for the treatment of chronic immune thrombocytopenia

Effective: 10/01/25

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FOSTEMSAVIR

Generic	Brand				
FOSTEMSAVIR TROMETHAMINE	RUKOBIA				

GUIDELINES FOR USE

Our guideline named **FOSTEMSAVIR (Rukobia)** requires the following rule(s) be met for approval:
You have human immunodeficiency virus type 1 (HIV-1) infection (an immune system disease caused by a virus)
You are 18 years of age or older
Rukobia will be used in combination with other antiretroviral(s) (medications that treat HIV)
You are treatment-experienced (previously treated)
Your HIV-1 infection is multidrug-resistant (does not respond to more than one HIV medication)
You are failing your current antiretroviral regimen due to resistance (does not respond), intolerance (side effect), or safety considerations

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FREMANEZUMAB-VFRM

Generic	Brand				
FREMANEZUMAB-VFRM	AJOVY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Episodic migraines (a type of headache)
- Chronic migraines (a type of headache)

If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 6 years of age or older
- Ajovy is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention

If you have chronic migraines (at least 15 headache days per month), approval also requires:
- You are 18 years of age or older
- Ajovy is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention

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FREMANEZUMAB-VFRM

RENEWAL CRITERIA

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:
The request is for the preventive treatment of migraines (a type of headache)
You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention
You meet ONE of the following:
- You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Ajovy therapy
- You have experienced a decrease in migraine (a type of headache) severity with Ajovy therapy
- You have experienced a decrease in migraine (a type of headache) duration with Ajovy therapy

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FRUQUINTINIB

Generic	Brand				
FRUQUINTINIB	FRUZAQLA				

GUIDELINES FOR USE

Our guideline named **FRUQUINTINIB (Fruzaqla)** requires the following rule(s) be met for approval:

You have metastatic colorectal cancer (mCRC: a type of digestive system cancer that has spread to other parts of the body)

You are 18 years of age or older

You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, CapeOx)

You have received previous treatment with an anti- vascular endothelial growth factor (VEGF) therapy (a type of treatment such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

Effective: 02/01/26

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FULVESTRANT

Generic	Brand				
FULVESTRANT	FASLODEX FULVESTRANT				

GUIDELINES FOR USE

Our guideline named **FULVESTRANT (Faslodex)** requires the following rule(s) be met for approval:
You have breast cancer
If you have hormone receptor (HR: a type of protein)-positive breast cancer, approval also requires:
Your cancer is advanced
You are a female and postmenopausal (after menopause)
The requested medication will be used as monotherapy (one medication treatment)
You have experienced disease progression (worsening) following endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)
If you have hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative breast cancer, approval also requires ONE of the following:
The requested medication will be used as monotherapy (one medication treatment) and you meet ALL of the following:
Your cancer is advanced
You are a female and postmenopausal (after menopause)
You have NOT previously been treated with an endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)
The requested medication will be used in combination with Kisqali (ribociclib) and you meet ALL of the following:
Your cancer is advanced or metastatic (has spread to other parts of the body)
You are a female and postmenopausal
You have NOT received a prior endocrine based therapy (such as letrozole, anastrozole, tamoxifen) OR you have experienced disease progression (worsening) on endocrine therapy
(Criteria continued on the next page)

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FULVESTRANT

GUIDELINES FOR USE (CONTINUED)

The requested medication will be used in combination with Itovebi (inavolisib) and Ibrance (palbociclib) and you meet ALL of the following:
- Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
- Your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

The requested medication will be used in combination with Ibrance (palbociclib) or Verzenio (abemaciclib) and you meet ALL of the following:
- Your cancer is advanced or metastatic
- You are a female
- You have experienced disease progression after an endocrine therapy (such as letrozole, anastrozole, tamoxifen)

Effective: 05/26/25

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FUROSEMIDE

Generic	Brand				
FUROSEMIDE	FUROSCIX				

GUIDELINES FOR USE

Our guideline named **FUROSEMIDE (Furoscix)** requires the following rule(s) be met for approval:

You have edema (swelling caused by fluid build-up in the body) with chronic (long-term) heart failure (a type of heart condition) or chronic kidney disease (including nephrotic syndrome [a type of kidney disorder])

You weigh at least 43 kilograms (94.6 pounds)

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or nephrologist (a type of kidney doctor)

Effective: 01/19/26

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FUROSEMIDE-FUROSCIX READYFLOW

Generic	Brand				
FUROSEMIDE	FUROSCIX READYFLOW				

GUIDELINES FOR USE

Our guideline named **FUROSEMIDE-FUROSCIX READYFLOW** requires the following rule(s) be met for approval:

A. You have edema (swelling caused by fluid build-up in the body) with chronic (long-term) heart failure (a type of heart condition) or chronic kidney disease (including nephrotic syndrome [a type of kidney disorder])
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or nephrologist (a type of kidney doctor)

Effective: 08/15/26

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FUROSEMIDE - LASIX ONYU

Generic	Brand				
FUROSEMIDE	LASIX ONYU				

GUIDELINES FOR USE

Our guideline named **FUROSEMIDE - LASIX ONYU** requires the following rule(s) be met for approval:
You have edema (swelling caused by fluid build-up in the body) with chronic (long-term) heart failure (a type of heart condition)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or nephrologist (a type of kidney doctor)

Effective: 02/09/26

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FUTIBATINIB

Generic	Brand				
FUTIBATINIB	LYTGOBI				

GUIDELINES FOR USE

Our guideline named **FUTIBATINIB (Lytgobi)** requires the following rule(s) be met for approval:
You have unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (a type of bile duct cancer inside the liver that is unable to be removed by surgery, has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
You are 18 years of age or older
You have been previously treated for unresectable, locally advanced or metastatic iCCA
You have fibroblast growth factor receptor 2 (FGFR2: a type of protein) gene fusions or other rearrangements
You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting Lytgobi and at the recommended scheduled times

Effective: 02/01/26

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GABAPENTIN

Generic	Brand				
GABAPENTIN	NEURONTIN, GABAPENTIN				

GUIDELINES FOR USE

Our guideline named **GABAPENTIN** requires the following rule(s) be met for approval:

A. You have a contraindication to (harmful for you to use) or are unable to swallow generic gabapentin capsules

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Effective: 07/01/26

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GALANTAMINE

Generic	Brand				
GALANTAMINE HBR	GALANTAMINE HYDROBROMIDE				

GUIDELINES FOR USE

Our guideline named **GALANTAMINE** requires the following rule(s) be met for approval:

A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
B. You have mild to moderate dementia (a type of memory disorder)
C. You have a contraindication to (harmful for you to use) or are unable to swallow galantamine tablets or capsules

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GALCANEZUMAB-GNLM

Generic	Brand				
GALCANEZUMAB-GNLM	EMGALITY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Episodic migraines (a type of headache)
- Chronic migraines (a type of headache)
- Episodic cluster headaches (a type of headache)

If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Emgality is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

If you have chronic migraines (15 or more headache days per month), approval also requires:
- You are 18 years of age or older
- Emgality is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

If you have episodic cluster headaches, approval also requires:
- You are 18 years of age or older
- Your symptoms were not adequately managed with abortive therapies (such as Imitrex [sumatriptan], Zomig [zolmitriptan], oxygen)

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GALCANEZUMAB-GNLM

RENEWAL CRITERIA

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

The request is for ONE of the following:
- Preventive treatment of migraines (a type of headache)
- Treatment of episodic cluster headache (a type of headache)

If the request is for preventive treatment of migraines, renewal also requires:
- You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention
- You meet ONE of the following:
  - You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Emgality therapy
  - You have experienced a decrease in migraine (a type of headache) severity with Emgality therapy
  - You have experienced a decrease in migraine (a type of headache) duration with Emgality therapy

If the request is for treatment of episodic cluster headaches, renewal also requires:
- You had improvement in episodic cluster headache frequency as compared to baseline (before treatment)

Effective: 04/01/26

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GANAXOLONE

Generic	Brand				
GANAXOLONE	ZTALMY				

GUIDELINES FOR USE

Our guideline named **GANAXOLONE (Ztalmy)** requires the following rule(s) be met for approval:
You have seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (a type of genetic disorder)
You are 2 years of age or older

Effective: 02/01/26

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GARADACIMAB-GXII

Generic	Brand				
GARADACIMAB-GXII	ANDEMBRY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GARADACIMAB-GXII (Andembry)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Andembry will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Andembry concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo], Dawnzera [donidalorsen])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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GARADACIMAB-GXII

RENEWAL CRITERIA

Our guideline named **GARADACIMAB-GXII (Andembry)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Andembry concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo], Dawnzera [donidalorsen])

Effective: 07/01/26

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GEFITINIB

Generic	Brand				
GEFITINIB	IRESSA, GEFITINIB				

GUIDELINES FOR USE

Our guideline named **GEFITINIB (Iressa)** requires the following rule(s) be met for approval:
You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (abnormal changes in a gene), as detected by a Food and Drug Administration (FDA)-approved test
You will NOT use the requested medication concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

Effective: 02/01/26

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GEMTUZUMAB OZOGAMICIN (NSA)

Generic	Brand			
GEMTUZUMAB OZOGAMICIN	MYLOTARG			

GUIDELINES FOR USE

Our guideline named **GEMTUZUMAB OZOGAMICIN (Mylotarg)** requires that ONE of the following rule(s) be met for approval:

You have newly-diagnosed CD33 (type of molecule that is used as a marker to diagnose AML) – positive acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many immature white blood cells) AND you are 1 month of age or older

You have relapsed (returning) or refractory (resistant) CD33 (type of molecule that is used as a marker to diagnose AML) -positive acute myeloid leukemia (AML) AND you are 2 years of age or older

Effective: 04/10/21

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GEPIRONE

Generic	Brand				
GEPIRONE HCL	EXXUA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GEPIRONE (Exxua)** requires the following rule(s) be met for approval:
You have major depressive disorder (MDD: a type of mental illness)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Fetzima (levomilnacipran) and Trintellix (vortioxetine)
You will NOT use Exxua concurrently (at the same time) with another 5-HT1A receptor agonist (such as buspirone)

RENEWAL CRITERIA

Our guideline named **GEPIRONE (Exxua)** requires the following rule(s) be met for renewal:
You have major depressive disorder (MDD: a type of mental illness)
You have had a response to or remission (reduction or disappearance of the signs and symptoms of a disease) of depressive symptoms with Exxua
You will NOT use Exxua concurrently (at the same time) with another 5-HT1A receptor agonist (such as buspirone)

Effective: 10/13/25

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GEPOTIDACIN

Generic	Brand				
GEPOTIDACIN MESYLATE	BLUJEPA				

GUIDELINES FOR USE

Our guideline named **GEPOTIDACIN (Blujepa)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
- Uncomplicated urogenital gonorrhea (a type of bacterial infection)

If you have uncomplicated urinary tract infection, approval also requires:
- You are a female
- You are 12 years of age or older
- Your uncomplicated urinary tract infection (a type of bacterial infection) is caused by susceptible *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis* (types of bacteria that can be treated with the medication)
- You meet ONE of the following:
  - Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
  - You have a documented culture demonstrating uncomplicated urinary tract infection (a type of bacterial infection is caused by a bacteria with sensitivity (lab test that shows what medications work on which bacteria) to gepotidacin AND resistance (medication will not work for that bacteria) or contraindication to (harmful for you to use) all alternatives (such as Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [such as amoxicillin-clavulanate]], cephalosporins [such as cephalexin], fluoroquinolones [such as ciprofloxacin])
  - Your request is for continuation of Blujepa therapy from an inpatient setting

If you have uncomplicated urogenital gonorrhea, approval also requires:
- You are 12 years of age or older
- Your infection has limited or no alternative treatment options
- Your infection is caused by a susceptible strain of *Neisseria gonorrhoeae*
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ceftriaxone

Effective: 02/01/26

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GILTERITINIB

Generic	Brand				
GILTERITINIB FUMARATE	XOSPATA				

GUIDELINES FOR USE

Our guideline named **GILTERITINIB (Xospata)** requires the following rule(s) be met for approval:

You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)

You are 18 years of age or older

You have a FMS-like tyrosine kinase 3 (FLT3: a type of gene) mutation (abnormal change), as detected by a Food and Drug Administration (FDA)-approved test

Effective: 02/01/26

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GIVINOSTAT

Generic	Brand				
GIVINOSTAT HYDROCHLORIDE	DUVYZAT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

RENEWAL CRITERIA

Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for renewal:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat
C. **If you are currently ambulatory (can walk), approval also requires:**
    1. You have shown improvement since starting Duvyzat, as measured by a standard set of ambulatory or functional status measures (such as 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
D. **If you are currently non-ambulatory (cannot walk), approval also requires:**
    1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since starting Duvyzat, as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

Effective: 08/01/24

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GIVOSIRAN (NSA)

Generic	Brand				
GIVOSIRAN	GIVLAARI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for approval:

A. You have acute hepatic porphyria (enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP/ALAD])
B. You are 18 years of age or older
C. You have genetic confirmation of AHP mutation (a change in your DNA that make up your gene), OR high (beyond reference range) urinary or plasma porphobilinogen (PBG), or aminolevulinic acid (ALA) (PBG and ALA: urine or blood tests that measure the level of porphyrins – a chemical that helps make hemoglobin in your body)
D. You have or are experiencing 4 or more recurrent (continues to return) attacks per year
E. The medication is prescribed by or given in consultation with a geneticist (doctor who specializes in conditions of gene disorders), hepatologist (doctor who specializes in treating the liver), hematologist (doctor who specializes in the study of blood, blood-forming organs and blood diseases), gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), neurologist (doctor who specializes in disorders of the nervous system), dermatologist (doctor who treats conditions of the skin, hair and nails), or a healthcare provider experienced in managing acute hepatic porphyria
F. Your doctor provided documentation of your weight

RENEWAL CRITERIA

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for renewal:

A. You have acute hepatic porphyria (AHP: enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP/ALAD])
B. You have achieved or maintained clinical (medical) benefit compared to baseline (such as less hemin use, less AHP attacks, improvement of AHP symptoms, etc.)
C. You have not received a liver transplant (replaced your bad liver with a healthy liver from another person)
D. Your doctor provided documentation of your weight

Effective: 07/01/26

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GLASDEGIB

Generic	Brand				
GLASDEGIB MALEATE	DAURISMO				

GUIDELINES FOR USE

Our guideline named **GLASDEGIB (Daurismo)** requires the following rule(s) be met for approval:

You have newly-diagnosed acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

Daurismo will be used in combination with low-dose cytarabine

You are 75 years of age or older, OR you have comorbidities (more than one disease) that prevents the use of intensive induction chemotherapy (start of high dose cancer treatment)

Effective: 02/01/26

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GLATIRAMER ACETATE

Generic	Brand				
GLATIRAMER ACETATE	COPAXONE, GLATOPA, GLATIRAMER ACETATE				

GUIDELINES FOR USE

Our guideline named **GLATIRAMER ACETATE (Copaxone, Glatopa)** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

You are 18 years of age or older

Effective: 02/01/26

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GLECAPREVIR/PIBRENTASVIR

Generic	Brand				
GLECAPREVIR/ PIBRENTASVIR	MAVYRET				

GUIDELINES FOR USE

Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:

You have acute (short-term) or chronic (long-term) hepatitis C virus (HCV: liver inflammation caused by a type of virus)

You are 3 years of age or older

You have a genotype 1, 2, 3, 4, 5, or 6 infection (types of hepatitis C virus)

You have an HCV RNA level (a measure of the amount of hepatitis C virus in your blood) within the past 6 months

You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])

You will NOT use Mavyret concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. John's wort)

You will NOT use Mavyret concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

If you have chronic hepatitis C virus and are treatment naive (no prior treatment), approval also requires ALL of the following:

You meet ONE of the following:

- You do not have cirrhosis (liver damage or scarring)
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
- You received a liver transplant (replaced your liver)
- You received a kidney transplant (replaced your kidney)

You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa or Harvoni, if you have a genotype 1, 4, 5, or 6 infection, OR you had an intolerance or contraindication to the preferred medication: Epclusa, if you have a genotype 2 or 3 infection

If you have chronic hepatitis C virus, are treatment-experienced (failed prior treatment) and prior therapy did not contain an NS5A inhibitor, approval also requires ONE of the following:

You have a genotype 1, 2, 4, 5, or 6 infection, and you have compensated cirrhosis (a condition where there is liver damage and scarring without major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) or you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]), and you do not have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

You have a genotype 3 infection, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

If you have chronic hepatitis C virus and are treatment-experienced (failed prior treatment), approval also requires ALL of the following:

You meet ONE of the following:

- You are less than 18 years of age AND had prior treatment with an interferon
- You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir]), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
- You have failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
- You have failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
- You have failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
- You are less than 18 years of age, have genotype 3, AND you had prior treatment with an interferon

You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa or Harvoni, if you have a genotype 1, 4, 5, or 6 infection, OR you had an intolerance or contraindication to the preferred medication Epclusa, if you have a genotype 2 or 3 infection

Mavyret will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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GLOFITAMAB-GXBM (NSA)

Generic	Brand				
GLOFITAMAB-GXBM	COLUMVI				

GUIDELINES FOR USE

Our guideline named **GLOFITAMAB-GXBM (Columvi)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of white blood cell cancer that has returned or is not responding to treatment), not otherwise specified (NOS), or large B-cell lymphoma (LBCL) arising from follicular lymphoma (a type of blood cancer)
B. You are 18 years of age or older
C. You previously received at least two lines of systemic therapy (treatment that travels throughout the body) (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
D. You will receive or have received a single dose of Gazyva (obinutuzumab) as a pretreatment prior to initiating Columvi
E. You have NOT previously received more than 12 cycles of Columvi

Effective: 10/01/23

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GLP-1 AGONIST

Generic	Brand				
EXENATIDE MICROSPHERES	BYDUREON BCISE				
EXENATIDE	BYETTA, EXENATIDE				
TIRZEPATIDE	MOUNJARO				
SEMAGLUTIDE	OZEMPIC, RYBELSUS				
DULAGLUTIDE	TRULICITY				
LIRAGLUTIDE	VICTOZA, LIRAGLUTIDE				

GUIDELINES FOR USE

Our guideline named **GLP-1 AGONIST (Bydureon BCise, Byetta [exenatide], Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza [liraglutide])** requires the following rule(s) be met for approval:

A. You have type 2 diabetes (a disorder with high blood sugar)

Effective: 07/01/26

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GLYCEROL PHENYLBUTYRATE

Generic	Brand				
GLYCEROL PHENYLBUTYRATE	RAVICTI, GLYCEROL PHENYLBUTYRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:

You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)

Your disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone

Your disorder is confirmed by enzymatic, biochemical, or genetic testing (types of lab tests)

The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction

You do NOT have a deficiency (low level) of N-acetylglutamate synthetase (NAGS: a type of enzyme) or acute hyperammonemia (sudden and short-term increase in ammonia levels to a critical level)

You have tried or have a contraindication to (harmful for you to use) Buphenyl (sodium phenylbutyrate)

RENEWAL CRITERIA

Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:

You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)

You had a clinical benefit compared to baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

Effective: 11/03/25

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GLYCOPYRRONIUM TOPICAL

Generic	Brand				
GLYCOPYRRONIUM TOSYLATE	QBREXZA				

GUIDELINES FOR USE

Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:
You have primary axillary hyperhidrosis (excessive underarm sweating)
You are 9 years of age or older
You will NOT use Qbrexza concurrently (at the same time) with other topical anticholinergics indicated for primary axillary hyperhidrosis (such as Sofdra [sofpironium bromide])

Effective: 04/01/26

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GOLIMUMAB - IV

Generic	Brand				
GOLIMUMAB	SIMPONI ARIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   ii. Enbrel (etanercept)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   vii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Taltz (ixekizumab)
   vii. Bimzelx (bimekizumab-bkzx)
   viii. Sotyktu (deucravacitinib)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   xi. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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GOLIMUMAB - IV

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
   3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

(Renewal criteria continued on next page)

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Enbrel (etanercept)
         iii. Otezla (apremilast)
         iv. Tremfya (guselkumab)
         v. Skyrizi (risankizumab-rzaa)
         vi. Xeljanz IR (tofacitinib immediate-release) (NOTE: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         vii. Rinvoq (upadacitinib) (NOTE: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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RENEWAL CRITERIA (CONTINUED)

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Taltz (ixekizumab)
   vii. Bimzelx (bimekizumab-bkzx)
   viii. Sotyktu (deucravacitinib)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Xeljanz (tofacitinib immediate-release or extended-release) (NOTE: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   xi. Rinvoq (upadacitinib) (NOTE: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - SQ

Generic	Brand				
GOLIMUMAB	SIMPONI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have moderate to severe ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)

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INITIAL CRITERIA (CONTINUED)

5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You weigh at least 15 kilograms (33 pounds)
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You are less than 5 years of age
   b. You are 5 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk
      ii. Adalimumab-aaty
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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GOLIMUMAB - SQ

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
   2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You meet ONE of the following:
      a. You are less than 5 years of age
      b. You are 5 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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GOLODIRSEN

Generic	Brand				
GOLODIRSEN	VYONDYS-53				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLODIRSEN (Vyondys 53)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of inherited muscle disorder)
B. You have a confirmed mutation (abnormal change in a type of gene) in the DMD gene that will respond to exon 53 skipping therapy (a type of therapy to treat DMD)
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of DMD at a DMD treatment center
D. You are ambulatory (able to walk)
E. You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

RENEWAL CRITERIA

Our guideline named **GOLODIRSEN (Vyondys 53)** requires ONE of the following rule(s) be met for renewal:

1. You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
2. You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

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GOSERELIN

Generic	Brand				
GOSERELIN ACETATE	ZOLADEX				

GUIDELINES FOR USE

Our guideline named **GOSERELIN (Zoladex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   Locally confined carcinoma (cancer) of the prostate
   Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   Moderate to severe pain from endometriosis (condition affecting the uterus)
   Dysfunctional uterine bleeding (abnormal uterine bleeding)
   Advanced breast cancer (breast cancer that has spread to nearby tissue or organs)

B. **If you have gender dysphoria, approval also requires:**
   Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. **If you have locally confined carcinoma of the prostate, approval also requires:**
   Zoladex will be used in combination with Eulexin (flutamide)

D. **If you have moderate to severe pain from endometriosis, approval also requires:**
   You are 18 years of age or older
   Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medications: a nonsteroidal anti-inflammatory drug (NSAID: such as ibuprofen, meloxicam, naproxen) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   You will NOT use Zoladex concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone], Lupron Depot [leuprolide])
   You have NOT received more than 6 months of treatment with Zoladex per lifetime

E. **If you have dysfunctional uterine bleeding, approval also requires:**
   Zoladex will be used as an endometrial-thinning agent prior to endometrial ablation (a type of surgical procedure)

F. **If you have advanced breast cancer, approval also requires:**
   You are a premenopausal (before menopause) or perimenopausal (time around menopause) female

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GUSELKUMAB

Generic	Brand				
GUSELKUMAB	TREMFYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Tremfya
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

(Initial criteria continued on next page)

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

E. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

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GUSELKUMAB

RENEWAL CRITERIA

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

E. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

Effective: 06/17/26

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HIGH CONCENTRATION HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

Generic	Brand				
MORPHINE SULFATE	MORPHINE SULFATE				
OXYCODONE HCL	OXYCODONE HCL				

GUIDELINES FOR USE

Our guideline named **HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (morphine sulfate, oxycodone hydrochloride)** requires the following rule(s) be met for approval:

A. You have pain severe enough to require opioid analgesic and for which alternative treatments are inadequate
B. You meet ONE of the following:
    1. You are enrolled in hospice OR you are receiving palliative care or end-of-life care
    2. You meet ALL of the following:
        a. You have previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
        b. You have trouble swallowing opioid tablets, capsules, or large volumes of liquid

Effective: 10/01/21

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HISTRELIN-SUPPRELIN LA (NSA)

Generic	Brand				
HISTRELIN ACETATE	SUPPRELIN LA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **HISTRELIN-SUPPRELIN LA** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:

- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
- Central precocious puberty (CPP: early sexual development in girls and boys)

If you are female and have central precocious puberty, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
- You have high levels of follicle-stimulating hormone (FSH: a type of hormone) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
- You are/were younger than 8 years of age when your condition started
- There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

If you are male and have central precocious puberty, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
- You have high levels of follicle-stimulating hormone (FSH: a type of hormone) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
- You are/were younger than 9 years of age when your condition started
- There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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HISTRELIN-SUPPRELIN LA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of gender dysphoria, please refer to the Initial Criteria section.

Our guideline named **HISTRELIN-SUPPRELIN LA** requires the following rule(s) be met for renewal:
You have central precocious puberty (CPP: early sexual development in girls and boys)
Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
You have not reached the actual age which corresponds to your current pubertal age

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Effective: 01/23/23

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HISTRELIN-VANTAS (NSA)

Generic	Brand				
HISTRELIN ACETATE	VANTAS				

GUIDELINES FOR USE

Our guideline named **HISTRELIN-VANTAS** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

Effective: 01/23/23

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HYALURONATE

Generic	Brand				
HYALURONATE SODIUM	EUFLEXXA, HYALGAN, GEL-ONE, GELSYN-3, ORTHOVISC, SUPARTZ FX, SYNOJOYNT, GENVISC 850, VISCO-3, TRIVISC, TRILURON, SODIUM HYALURONATE				
HYALURONATE SODIUM, STABILIZED	MONOVISC, DUROLANE				
HYALURONATE, MODIFIED, NON-CROSSLINK, HYALURONAN	HYMOVIS, HYMOVIS ONE				
HYLAN G-F 20	SYNVISC, SYNVISC-ONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz FX, Synojoynt, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for approval:
You have osteoarthritis (a type of joint condition) of the knee
You are 21 years of age or older
You have failed a 6-week trial of non-pharmacologic (non-drug) therapy (such as education, exercise, use of insoles or braces, weight loss, physical therapy [exercises to restore health])
(Initial criteria continued on next page)

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HYALURONATE

INITIAL CRITERIA (CONTINUED)

If the request is for Euflexxa, Synvisc, or Synvisc-One, approval also requires ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) an intra-articular (injected within the joint) steroid (such as methylprednisolone acetate, triamcinolone acetonide)
- You have tried or have a contraindication to (harmful for you to use) a topical non-steroidal anti-inflammatory drug (NSAID) (such as diclofenac)
- You have tried or have a contraindication to (harmful for you to use) an oral non-steroidal anti-inflammatory drug (NSAID) (such as meloxicam, diclofenac)
- You have tried or have a contraindication to (harmful for you to use) acetaminophen

If the request is for Durolane, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz FX, Triluron, Trivisc, Visco-3, Synojoynt, or Sodium Hyaluronate, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) Euflexxa AND Synvisc or Synvisc-One
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) an intra-articular (injected within the joint) steroid (such as methylprednisolone acetate, triamcinolone acetonide)
  - You have tried or have a contraindication to (harmful for you to use) a topical non-steroidal anti-inflammatory drug (NSAID) (such as diclofenac)
  - You have tried or have a contraindication to (harmful for you to use) an oral non-steroidal anti-inflammatory drug (NSAID) (such as meloxicam, diclofenac)
  - You have tried or have a contraindication to (harmful for you to use) acetaminophen

RENEWAL CRITERIA

Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz FX, Synojoynt, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for renewal:
It has been at least 6 months since your last treatment on the same knee

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HYDROCHLOROTHIAZIDE

Generic	Brand				
HYDROCHLOROTHIAZIDE	INZIRQO				

GUIDELINES FOR USE

Our guideline named **HYDROCHLOROTHIAZIDE (Inzirqo)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Hypertension (high blood pressure)
- Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), hepatic cirrhosis (liver damage and scarring), or renal (kidney) disease (including nephrotic syndrome [a type of kidney disorder])

If you have hypertension, approval also requires:

- You have a contraindication to (harmful for you to use) or are unable to swallow hydrochlorothiazide tablets

If you have edema associated with congestive heart failure, hepatic cirrhosis, or renal disease (including nephrotic syndrome), approval also requires:

- You have a contraindication to (harmful for you to use) or are unable to swallow hydrochlorothiazide tablets

Effective: 04/07/25

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HYDROCORTISONE

Generic	Brand				
HYDROCORTISONE	ALKINDI SPRINKLE				

GUIDELINES FOR USE

Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:
You have adrenocortical insufficiency (a type of hormone disorder)
You are less than 18 years of age
You are unable to take the tablet form of hydrocortisone (such as you need a lower strength, you have difficulty swallowing)

Effective: 02/01/26

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HYDROMORPHONE ER

Generic	Brand			
HYDROMORPHONE HCL	EXALGO, HYDROMORPHONE ER			

GUIDELINES FOR USE

Our guideline named **HYDROMORPHONE ER (Exalgo)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose (equal pain relieving dose) of another opioid
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

Effective: 03/04/22

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HYDROXYUREA-XROMI

Generic	Brand				
HYDROXYUREA	XROMI				

GUIDELINES FOR USE

Our guideline named **HYDROXYUREA-XROMI** requires the following rule(s) be met for approval:

A. You have sickle cell anemia (a type of blood disorder)
B. You are 6 months to 17 years of age
C. You have recurrent moderate to severe painful crises (repeated episodes of extreme pain)
D. You have a contraindication to (harmful for you to use) or are unable to swallow generic hydroxyurea capsules

Effective: 07/01/26

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IBALIZUMAB-UIYK (NSA)

Generic	Brand				
IBALIZUMAB-UIYK	TROGARZO				

GUIDELINES FOR USE

Our guideline named **IBALIZUMAB-UIYK (Trogarzo)** requires the following rule(s) be met for approval:

A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
B. You are 18 years of age or older
C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
D. You are treatment experienced (previously treated)
E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
F. You are failing your current antiretroviral regimen

Effective: 10/01/20

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IBREXAFUNGERP

Generic	Brand				
IBREXAFUNGERP CITRATE	BREXAFEMME				

GUIDELINES FOR USE

Our guideline named **IBREXAFUNGERP (Brexafemme)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of vulvovaginal candidiasis (VVC: vaginal yeast infection)
   2. Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC: repeated vaginal yeast infection)

B. **If you are using Brexafemme for the treatment of vulvovaginal candidiasis, approval also requires:**
   1. You are a post-menarchal (you have started having your period) female
   2. You have tried or have a contraindication to (harmful for) oral fluconazole AND an intravaginal azole (type of drug that is inserted into the vagina and used to treat yeast infections such as terconazole cream)

C. **If you are using Brexafemme for the reduction in the incidence of recurrent vulvovaginal candidiasis, approval also requires:**
   1. You are a post-menarchal (you have started having your period) female
   2. You have tried or have a contraindication to (harmful for) oral fluconazole (you had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
   3. You are NOT currently on oteseconazole for RVVC
   4. You meet ONE of the following:
      a. You have not previously received Brexafemme AND you had 3 or more episodes of RVVC in the past 12 months
      b. You have been previously treated with Brexafemme and meet ALL of the following:
         i. You have successfully completed a course of Brexafemme for prevention of RVVC
         ii. You are either being treated or have just completed treatment for a new recurrence of VVC

Effective: 04/01/23

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IBRUTINIB

Generic	Brand			
IBRUTINIB	IMBRUVICA			

GUIDELINES FOR USE

Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   3. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   4. Chronic graft-versus-host disease (cGVHD: a type of long-term immune disorder)

B. **If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenstrom's macroglobulinemia, approval also requires:**
   1. You are 18 years of age or older

C. **If you have chronic graft-versus-host disease, approval also requires:**
   1. You are 1 year of age or older
   2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
   3. You will NOT use Imbruvica concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil)

NOTE: Requests for Imbruvica (ibrutinib) 560 mg tablet will not be approved. This strength does not have a Food and Drug Administration (FDA)-approved indication.

Effective: 02/24/25

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ICATIBANT

Generic	Brand				
ICATIBANT ACETATE	FIRAZYR, SAJAZIR, ICATIBANT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 18 years of age or older
C. The requested medication will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use the requested medication concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema: a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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ICATIBANT

RENEWAL CRITERIA

Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use the requested medication concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

Effective: 07/01/26

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ICOTROKINRA

Generic	Brand				
ICOTROKINRA HCL	ICOTYDE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ICOTROKINRA (Icotyde)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You will NOT use Icotyde concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, TYK2 [tyrosine kinase 2] inhibitor [such as Sotyktu (deucravacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
E. You meet ONE of the following:
    1. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
    2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
    3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
F. You meet ONE of the following:
    1. You were previously stable on another biologic and are switching to Icotyde
    2. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA)
    3. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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ICOTROKINRA

RENEWAL CRITERIA

Our guideline named **ICOTROKINRA (Icotyde)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
C. You will NOT use Icotyde concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, TYK2 [tyrosine kinase 2] inhibitor [such as Sotyktu (deucravacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

Effective: 07/01/26

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IDELALISIB

Generic	Brand				
IDELALISIB	ZYDELIG				

GUIDELINES FOR USE

Our guideline named **IDELALISIB (Zydelig)** requires the following rule(s) be met for approval:
You have relapsed (disease has returned) chronic lymphocytic leukemia (CLL: a type of blood cancer)
Zydelig will be used in combination with rituximab

Effective: 02/01/26

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ILOPROST

Generic	Brand				
ILOPROST TROMETHAMINE	VENTAVIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following clinical standard of care medications from different drug classes:
    1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
    2. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
    3. Oral cGMP stimulator (such as Adempas [riociguat])
    4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

RENEWAL CRITERIA

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Effective: 05/20/26

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IMATINIB

Generic	Brand				
IMATINIB MESYLATE	GLEEVEC, IMKELDI, IMATINIB MESYLATE				

GUIDELINES FOR USE

Our guideline named **IMATINIB (Gleevec, Imkeldi)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML: a type of blood cancer)
- Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cancer)
- Myelodysplastic/myeloproliferative disease (MDS/MPD: a type of blood cancer)
- Aggressive systemic mastocytosis (ASM: a type of blood disorder)
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) (types of inflammatory cancer)
- Dermatofibrosarcoma protuberans (DFSP: a type of rare skin tumor)
- Gastrointestinal stromal tumor (GIST: type of digestive tumor)

If the request is for Imkeldi solution, approval also requires that you are unable to swallow generic imatinib tablets

If you have Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML), approval also requires:

You meet ONE of the following:

- Your Ph+ CML is in chronic phase AND you are newly diagnosed (such as you are starting or previously started the requested treatment at the time your condition was identified)
- Your Ph+ CML is in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy

You have NOT received previous treatment with another tyrosine kinase inhibitor (such as Tasigna [nilotinib], Sprycel [dasatinib], Bosulif [bosutinib], Iclusig [ponatinib])

You had a mutational analysis (a type of lab test) prior to the start of therapy AND the requested medication is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

(Criteria continued on next page)

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

If you have Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:
- You meet ONE of the following:
  - You are 18 years of age or older, AND your Ph+ ALL has relapsed or is refractory (cancer that has returned or has not responded to treatment)
  - You are newly diagnosed (such as you are starting or previously started the requested treatment at the time your condition was identified) AND the requested medication will be used in combination with chemotherapy (a type of cancer treatment)

If you have myelodysplastic/myeloproliferative disease, approval also requires:
- You are 18 years of age or older
- Your disease is associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements (a type of gene mutation)

If you have aggressive systemic mastocytosis, approval also requires:
- You are 18 years of age or older
- Your disease is without the D816V c-Kit mutation (abnormal change in a type of gene) or the c-Kit mutational status is unknown

If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:
- You are 18 years of age or older

If you have dermatofibrosarcoma protuberans, approval also requires:
- You are 18 years of age or older
- Your cancer is unresectable, recurrent, and/or metastatic (cancer that cannot be completely removed by surgery, has returned, and/or has spread to other parts of the body)

If you have gastrointestinal stromal tumor (GIST), approval also requires:
- Your tumor is Kit (CD117: a type of protein) positive
- You meet ONE of the following:
  - Your cancer is unresectable and/or metastatic malignant (cannot be completely removed by surgery and/or has spread to other parts of the body)
  - You are 18 years of age or older AND the requested medication will be used as adjuvant (additional) treatment following complete gross resection (removal by surgery)
- For requests of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a gastrointestinal stromal tumor (GIST: type of digestive tumor) expressing a KIT exon 9 mutation (abnormal change in a type of gene)

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IMETELSTAT (NSA)

Generic	Brand				
IMETELSTAT SODIUM	RYTELO				

GUIDELINES FOR USE

Our guideline named **IMETELSTAT (Rytelo)** requires the following rule(s) be met for approval:
You have myelodysplastic syndrome (MDS: a type of blood cancer)
You are 18 years of age or older
Your cancer is low- to intermediate-1 risk
You have transfusion-dependent anemia (a type of blood condition) requiring at least 4 red blood cell (RBC) units over 8 weeks
Your cancer did not respond to treatment with erythropoiesis-stimulating agents (ESA: a type of medication that increases the production of red blood cells, such as Epogen [epoetin alfa]) OR you are not able to be treated with ESA

Effective: 08/01/24

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IMIGLUCERASE

Generic	Brand				
IMIGLUCERASE	CEREZYME				

GUIDELINES FOR USE

Our guideline named **IMIGLUCERASE (Cerezyme)** requires the following rule(s) be met for approval:

You have Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)

You have non-central nervous system (CNS) manifestations (symptoms not involving the brain and spinal cord)

You have Type 1 (no brain involvement) or Type 3 (slowly progressive brain involvement) Gaucher disease

Effective: 02/09/26

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IMLUNESTRANT

Generic	Brand				
IMLUNESTRANT TOSYLATE	INLURIYO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IMLUNESTRANT (Inluriyo)** requires the following rule(s) be met for approval:

A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. Your disease is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene)
C. You have had disease progression (worsening) following at least ONE line of endocrine therapy (a type of hormone therapy such as anastrozole, letrozole)
D. Therapy is prescribed by or in consultation with an oncology specialist (a type of cancer doctor)
E. You will NOT use Inluriyo concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Veppanu [vepdegestrant])

RENEWAL CRITERIA

Our guideline named **IMLUNESTRANT (Inluriyo)** requires the following rule(s) be met for renewal:

A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. Your disease is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene)
C. You have experienced clinical benefit while on therapy as shown by a partial (cancer has shrunk but did not go away) or complete response (cancer went away completely) OR stable disease (disease has stopped growing or spreading)
D. You will NOT use Inluriyo concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Veppanu [vepdegestrant])

Effective: 08/21/26

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IMMUNE GLOBULIN - GAMASTAN (S-D)

Generic	Brand				
IMMUNE GLOBUL G (IGG)/GLYCINE	GAMASTAN, GAMASTAN S-D				

GUIDELINES FOR USE

Our guideline named **IMMUNE GLOBULIN - GAMASTAN (S-D)** requires the following rule(s) be met for approval:

A. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella (types of viral infections)

Effective: 05/20/26

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IMMUNE GLOBULIN - IV

Generic	Brand				
IMMUNE GLOBULIN (HUMAN) IV	ALYGLO				
	ASCENIV				
	BIVIGAM, FLEBOGAMMA DIF, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN				
	OCTAGAM				
	PANZYGA				
	QIVIGY				
	YIMMUGO				

GUIDELINES FOR USE

Our guideline named **IMMUNE GLOBULIN - IV (Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammagard S-D, Gammaplex, Octagam, Panzyga, Privigen, Qivigy, Yimmugo)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Primary immunodeficiency disease (genetic disease where the immune system is weak)
- Immune (idiopathic) thrombocytopenic purpura (a type of blood disorder)
- Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
- Multifocal motor neuropathy (MMN: a nerve disorder with increasing muscle weakness)
- Kawasaki syndrome (inflammation in the walls of blood vessels in the body)
- B-cell chronic lymphocytic leukemia (CLL: blood and bone marrow cancer of immune cells) with hypogammaglobulinemia (low levels of immunoglobulins)
- Autoimmune hemolytic anemia (AIHA: body destroys red blood cells more rapidly than it produces them)
- Pure red cell aplasia (PRCA: bone marrow stops making red blood cells)
- Guillain-Barre syndrome (GBS: immune system attacks the nerves)
- Myasthenia gravis (a type of chronic autoimmune disorder)
- Autoimmune Graves' ophthalmopathy (a type of eye disease)
- Cytomegalovirus-induced pneumonitis (lung tissue inflammation caused by a virus) related to a solid organ transplant
- Prevention of bacterial infection in an HIV (human immunodeficiency virus: an immune system disease caused by a virus)- infected child

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

Reduction of secondary infections in pediatric HIV (human immunodeficiency virus: an immune system disease caused by a virus) infections
Dermatomyositis (a type of muscle and skin disorder) or polymyositis (a type of inflammatory muscle disease)
Autoimmune uveitis (birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
IgM (immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (a type of nerve damage)
Stiff-man syndrome (a nerve disorder with increasing muscle stiffness [rigidity] and repeated episodes of painful muscle spasms)
Neonatal sepsis (blood infection in infants)
Rotaviral enterocolitis (severe diarrhea among infants and young children)
Toxic shock syndrome (a life-threatening complication of certain bacterial infections)
Enteroviral meningoencephalitis (inflammation of the brain and surrounding tissues caused by a virus)
Toxic epidermal necrolysis or Stevens-Johnson syndrome (types of serious bacterial skin infections)
Autoimmune mucocutaneous blistering disease (AMBD) (group of serious skin conditions that start with blisters on the skin such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

If the request is for Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammaplex, Panzyga, Qivigy, or Yimmugo approval also requires:

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gammagard S-D, Gammagard (Liquid), Gammagard Liquid ERC, Gamunex-C, Octagam, Privigen

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IMMUNE GLOBULIN - IV/SQ

Generic	Brand				
IMMUN GLOB G(IGG)/GLY/IGA OV50	GAMMAGARD LIQUID				
IMMUNE GLOBUL G/GLY/IGA AVG 46	GAMMAKED, GAMUNEX-C				
IMMUN GLOB G(IGG)/GLY/IGA 0-50	GAMMAGARD LIQUID ERC				

GUIDELINES FOR USE

Our guideline named **IMMUNE GLOBULIN - IV/SQ (Gammagard [Liquid], Gamunex-C, Gammaked, Gammagard Liquid ERC)** requires the following rule(s) be met for approval:

For subcutaneous (SQ) injection, approval requires:

You have ONE of the following:

- Primary immunodeficiency disease (genetic disease where the immune system is weak)
- Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

If the request is for Gammaked, approval also requires:

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gamunex-C, Gammagard (Liquid), Gammagard Liquid ERC, Xembify

For intravenous (IV) injection, approval requires:

You have ONE of the following:

- Primary immunodeficiency disease (genetic disease where the immune system is weak)
- Immune (idiopathic) thrombocytopenic purpura (a type of blood disorder)
- Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
- Multifocal motor neuropathy (MMN: a nerve disorder with increasing muscle weakness)
- Kawasaki syndrome (inflammation in the walls of blood vessels in the body)
- B-cell chronic lymphocytic leukemia (CLL: blood and bone marrow cancer of immune cells) with hypogammaglobulinemia (low levels of immunoglobulins)
- Autoimmune hemolytic anemia (AIHA: body destroys red blood cells more rapidly than it produces them)
- Pure red cell aplasia (PRCA: bone marrow stops making red blood cells)
- Guillain-Barre syndrome (GBS: immune system attacks the nerves)

(Criteria continued on next page)

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GUIDELINES FOR USE (CONTINUED)

- Myasthenia gravis (a type of chronic autoimmune disorder)
- Autoimmune Graves' ophthalmopathy (a type of eye disease)
- Cytomegalovirus-induced pneumonitis (lung tissue inflammation caused by a virus) related to a solid organ transplant
- Prevention of bacterial infection in an HIV (human immunodeficiency virus: an immune system disease caused by a virus)- infected child
- Reduction of secondary infections in pediatric HIV (human immunodeficiency virus: an immune system disease caused by a virus) infections
- Dermatomyositis (a type of muscle and skin disorder) or polymyositis (a type of inflammatory muscle disease)
- Autoimmune uveitis (birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
- Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
- IgM (immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (a type of nerve damage)
- Stiff-man syndrome (a nerve disorder with increasing muscle stiffness [rigidity] and repeated episodes of painful muscle spasms)
- Neonatal sepsis (blood infection in infants)
- Rotaviral enterocolitis (severe diarrhea among infants and young children)
- Toxic shock syndrome (a life-threatening complication of certain bacterial infections)
- Enteroviral meningoencephalitis (inflammation of the brain and surrounding tissues caused by a virus)
- Toxic epidermal necrolysis or Stevens-Johnson syndrome (types of serious bacterial skin infections)
- Autoimmune mucocutaneous blistering disease (AMBD) (group of serious skin conditions that start with blisters on the skin such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

If the request is for Gammaked, approval also requires:

- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gammagard S-D, Gammagard (Liquid), Gammagard Liquid ERC, Gamunex-C, Octagam, Privigen

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IMMUNE GLOBULIN - SQ

Generic	Brand				
IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS	CUTAQUIG				
	CUVITRU				
	HIZENTRA				
	HYQVIA				
	XEMBIFY				

GUIDELINES FOR USE

Our guideline named **IMMUNE GLOBULIN - SQ (Cutaquig, Cuvitru, Hizentra, Hyqvia, Xembify)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Primary immunodeficiency disease (genetic disease where the immune system is weak)
- Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

If the request is for Cutaquig, Cuvitru, Hizentra, or Hyqvia, approval also requires:

- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gamunex-C, Gammagard (Liquid), Gammagard Liquid ERC, Xembify

Effective: 02/09/26

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INAVOLISIB

Generic	Brand				
INAVOLISIB	ITOVEBI				

GUIDELINES FOR USE

Our guideline named **INAVOLISIB (Itovebi)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic breast cancer (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
C. Your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
D. Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
E. You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

Effective: 05/05/25

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INCOBOTULINUM TOXIN A

Generic	Brand				
INCOBOTULINUM TOXIN A	XEOMIN				

GUIDELINES FOR USE

Our guideline named **INCOBOTULINUM TOXIN A (Xeomin)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chronic sialorrhea (drooling or excessive salivation)
   2. Cervical dystonia (a type of muscle condition)
   3. Blepharospasm (a type of eye disease)
   4. Upper limb spasticity (stiffness or tightness of your muscles)

B. **If you have chronic sialorrhea or upper limb spasticity, approval also requires:**
   1. You are 2 years of age or older

C. **If you have cervical dystonia or blepharospasm, approval also requires:**
   1. You are 18 years of age or older

NOTE: This medication will not be approved for a cosmetic indication (for example wrinkles - glabellar lines [wrinkle between the eyebrows], lateral canthal lines [wrinkles in outer corner of eye], forehead lines).

Effective: 07/15/26

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INEBILIZUMAB-CDON

Generic	Brand				
INEBILIZUMAB-CDON	UPLIZNA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
- Immunoglobulin G4-related disease (IgG4-RD: a type of inflammatory disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

If you have neuromyelitis optica spectrum disorder, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
- You have a positive serologic (blood) test for the anti-aquaporin-4 (AQP4: a type of protein) antibody
- You will NOT use Uplizna concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])
- You have at least ONE of the following core clinical characteristics:
  - Optic neuritis (a type of brain disorder)
  - Acute myelitis (a type of brain disorder)
  - Area postrema syndrome (a type of brain disorder)
  - Acute brainstem syndrome (a type of brain disorder)
  - Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (a type of brain disorder) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

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INEBILIZUMAB-CDON

INITIAL CRITERIA (CONTINUED)

If you have Immunoglobulin G4-related disease, approval also requires:
- You are 18 years of age or older

If you have generalized myasthenia gravis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- Your diagnosis is confirmed by a positive serologic test (a type of blood test) for anti-acetylcholine receptor antibody (AChR-Ab+: an indicator of myasthenia gravis) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+: an indicator of myasthenia gravis)
- You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
- You will NOT use Uplizna concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis (a chronic autoimmune disorder)
- You have tried or have a contraindication to (harmful for you to use) ONE standard of care corticosteroid (such as prednisone)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)
- You meet ONE of the following criteria:
  - You have tried or have a contraindication to (harmful for you to use) TWO standard of care non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
  - You have tried or have a contraindication to (harmful for you to use) ONE standard of care non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange (types of blood therapy)

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INEBILIZUMAB-CDON

RENEWAL CRITERIA

NOTE: For the diagnosis of Immunoglobulin G4-related disease, please refer to the Initial Criteria section.

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

If you have neuromyelitis optica spectrum disorder, renewal also requires:

- You have experienced a clinical benefit (reduction in relapse frequency from baseline [before treatment] or a decrease in NMOSD-related hospitalizations)
- You will NOT use Uplizna concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

If you have generalized myasthenia gravis, renewal also requires:

- You have shown a clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
- You will NOT use Uplizna concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis (a chronic autoimmune disorder)

Effective: 01/01/26

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INFLIXIMAB

Generic	Brand				
INFLIXIMAB	REMICADE, INFLIXIMAB				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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INITIAL CRITERIA (CONTINUED)

4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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INITIAL CRITERIA (CONTINUED)

5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have severe plaque psoriasis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

F. **If you have moderate to severe Crohn's disease, approval also requires:**
1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk
      ii. Adalimumab-aaty
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Tremfya (guselkumab)
      c. Skyrizi (risankizumab-rzaa)
      d. Enbrel (etanercept)
      e. Otezla (apremilast)
      f. Taltz (ixekizumab)
      g. Sotyktu (deucravacitinib)
      h. Bimzelx (bimekizumab-bkzx)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Icotyde (icotrokinra)

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RENEWAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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INFLIXIMAB-ABDA

Generic	Brand				
INFLIXIMAB-ABDA	RENFLEXIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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INITIAL CRITERIA (CONTINUED)

4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

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INITIAL CRITERIA (CONTINUED)

5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have severe plaque psoriasis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
4. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   d. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   e. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   f. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

F. **If you have moderate to severe Crohn's disease, approval also requires:**
1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk
      ii. Adalimumab-aaty
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
   2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Tremfya (guselkumab)
      c. Skyrizi (risankizumab-rzaa)
      d. Enbrel (etanercept)
      e. Otezla (apremilast)
      f. Taltz (ixekizumab)
      g. Sotyktu (deucravacitinib)
      h. Bimzelx (bimekizumab-bkzx)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Icotyde (icotrokinra)

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RENEWAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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INFLIXIMAB-AXXQ

Generic	Brand				
INFLIXIMAB-AXXQ	AVSOLA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
   4. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Tremfya (guselkumab)
      c. Skyrizi (risankizumab-rzaa)
      d. Enbrel (etanercept)
      e. Otezla (apremilast)
      f. Taltz (ixekizumab)
      g. Sotyktu (deucravacitinib)
      h. Bimzelx (bimekizumab-bkzx)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Icotyde (icotrokinra)
   6. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
   2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Tremfya (guselkumab)
      c. Skyrizi (risankizumab-rzaa)
      d. Enbrel (etanercept)
      e. Otezla (apremilast)
      f. Taltz (ixekizumab)
      g. Sotyktu (deucravacitinib)
      h. Bimzelx (bimekizumab-bkzx)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Icotyde (icotrokinra)

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RENEWAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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INFLIXIMAB-DYYB - IV

Generic	Brand				
INFLIXIMAB-DYYB	INFLECTRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB-DYYB - IV (Inflectra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
   4. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Tremfya (guselkumab)
      c. Skyrizi (risankizumab-rzaa)
      d. Enbrel (etanercept)
      e. Otezla (apremilast)
      f. Taltz (ixekizumab)
      g. Sotyktu (deucravacitinib)
      h. Bimzelx (bimekizumab-bkzx)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Icotyde (icotrokinra)
   6. You meet ONE of the following:
      g. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      h. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      i. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   3. You meet ONE of the following:
      b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         A. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         B. Skyrizi (risankizumab-rzaa)
         C. Tremfya (guselkumab)
         D. Omvoh (mirikizumab-mrkz)
         E. Adalimumab-ryvk/adalimumab-aaty
         F. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         G. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-DYYB - IV (Inflectra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   4. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   5. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   6. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   7. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      c. Otezla (apremilast)
      d. Tremfya (guselkumab)
      e. Skyrizi (risankizumab-rzaa)
      f. Taltz (ixekizumab)
      g. Bimzelx (bimekizumab-bkzx)
      h. Sotyktu (deucravacitinib)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

(Renewal criteria continued on next page)

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
   2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Tremfya (guselkumab)
      c. Skyrizi (risankizumab-rzaa)
      d. Enbrel (etanercept)
      e. Otezla (apremilast)
      f. Taltz (ixekizumab)
      g. Sotyktu (deucravacitinib)
      h. Bimzelx (bimekizumab-bkzx)
      i. Adalimumab-ryvk/adalimumab-aaty
      j. Icotyde (icotrokinra)

(Renewal criteria continued on next page)

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Adalimumab-ryvk
         ii. Adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-DYYB - SQ

Generic	Brand				
INFLIXIMAB-DYYB	ZYMFENTRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for approval:
You have ONE of the following:

2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe ulcerative colitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
4. You meet ONE of the following:
   a. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

(Initial criteria continued on the next page)

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
4. You meet ONE of the following:
   a. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for renewal:

You have ONE of the following:

1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You meet ONE of the following:
   i. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

(Renewal criteria continued on next page)

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 08/01/26

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INGENOL

Generic	Brand				
INGENOL MEBUTATE	PICATO				

GUIDELINES FOR USE

Do not approve requests for Picato gel.

(NOTE: Picato discontinued due to safety concerns and increased risk of cancer.)

Effective: 10/01/21

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INHALED INSULIN

Generic	Brand			
INSULIN REGULAR, HUMAN	AFREZZA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Type 1 diabetes mellitus (a disorder with high blood sugar)
   2. Type 2 diabetes mellitus (a disorder with high blood sugar)

B. **If you have type 1 diabetes mellitus, approval also requires:**
   1. You are 6 years of age or older
   2. You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
   3. Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)
   4. You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev

C. **If you have type 2 diabetes mellitus, approval also requires:**
   1. You are 6 years of age or older
   2. You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
   3. You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev
   4. Your prescriber has indicated that you are physically unable to or unwilling to use injectable insulin

NOTE: Afrezza will NOT be approved if you have any of the following conditions: chronic lung disease (type of long-term lung disease), active lung cancer, currently in diabetic ketoacidosis (condition where body breaks down fat too fast), you are currently smoking or you quit smoking within the past 6 months.

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INHALED INSULIN

RENEWAL CRITERIA

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Type 1 diabetes mellitus (a disorder with high blood sugar)
   2. Type 2 diabetes mellitus (a disorder with high blood sugar)

B. **If you have type 1 diabetes, renewal also requires:**
   1. You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
   2. Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)
   3. Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)

C. **If you have type 2 diabetes, renewal also requires:**
   1. You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
   2. Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)

Effective: 06/24/26

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INOTERSEN

Generic	Brand			
INOTERSEN SODIUM	TEGSEDI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Amvuttra
G. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (*transthyretin*) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

RENEWAL CRITERIA

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
C. You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

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INOTUZUMAB OZOGAMICIN (NSA)

Generic	Brand			
INOTUZUMAB OZOGAMICIN	BESPONSA			

GUIDELINES FOR USE

Our guideline named **INOTUZUMAB OZOGAMICIN (Besponsa)** requires the following rule(s) be met for approval:
You have relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL: a type of blood cancer that has returned or did not respond to treatment)
You are 1 year of age or older
You have NOT previously received 6 cycles of Besponsa

Effective: 04/01/24

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INSULIN DEVICES

Generic	Brand				
INSULIN INFUSION DISPOSABLE PUMP, INSULIN INFUSION SET/CARTRIDGE, INSULIN PUMP/CART/SET/SYR/NEED	MODD1 PATIENT WELCOME KIT, PIVOT INSULIN PUMP STARTER KIT				
	MODD1 SUPPLY KIT, PIVOT SUPPLY KIT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INSULIN DEVICES (MODD1, Pivot)** requires the following rule(s) be met for approval:

A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
B. You are 18 years of age or older
C. The requested device is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. You have completed a comprehensive diabetes education program within the previous 24 months
E. You follow a maintenance program of at least 3 injections of insulin per day and have required frequent self-adjustments of your insulin dose for the past 6 months
F. You have required glucose self-testing of at least 4 times per day on average in the previous 2 months
G. You have tried ONE of the following preferred devices: CeQur, Omnipod 5, Omnipod DASH, V-Go, Twiist
H. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: a type of lab test) that is greater than 7%
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations (variations) in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
I. **If you are requesting more than 10 cartridges per month, approval also requires:**
    1. You are using more than 300 units of insulin per 72 hours

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INSULIN DEVICES

RENEWAL CRITERIA

Our guideline named **INSULIN DEVICES (MODD1, Pivot)** requires the following rule(s) be met for renewal:

A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
B. You have shown a positive response to therapy
C. You are adherent (keeping up with) your doctor follow-up visits
D. **If you are requesting more than 10 cartridges per month, approval also requires:**
    1. You are using more than 300 units of insulin per 72 hours

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Effective: 08/01/26

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INSULIN PUMPS

Generic	Brand				
SUBCUTANEOUS INSULIN PUMP	T:SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, TANDEM T:SLIM STARTER KIT, TANDEM MOBI SYSTEM, MINIMED 670G, MINIMED 770G, MINIMED 780G, MINIMED 630G, ILET INSULIN PUMP				
INSULIN INFUSION PUMP	MINIMED FLEX				
INSULIN INFUSION PUMP SUPPLIES	MINIMED EXTENDED SUPPLY KIT				

GUIDELINES FOR USE

Our guideline named **INSULIN PUMPS** requires the following rule(s) be met for approval:

A. The requested insulin pump is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
B. You have completed a comprehensive diabetes education program within the previous 24 months
C. You follow a maintenance program of at least 3 injections of insulin per day and have required frequent self-adjustments of your insulin dose for the past 6 months
D. You have required glucose self-testing at least 4 times per day on average in the previous 2 months
E. You have NOT received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: a type of lab test) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL

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5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

G. **If you are requesting the T:Slim X2, Tandem T:Slim Starter Kit (T:Slim X2 Starter 7.10), OR Tandem Mobi, approval also requires:**
   1. You are 2 years of age or older

H. **If you are requesting the T:Slim X2 with Basal-IQ, approval also requires:**
   1. You are 6 years of age or older

I. **If you are requesting the T:Slim X2 with Control-IQ, approval also requires ONE of the following:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar) AND you are 2 years of age or older
   2. You have type 2 diabetes mellitus (a disorder with high blood sugar) AND you are 18 years of age or older

J. **If you are requesting the MiniMed 670G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 7 years of age or older

K. **If you are requesting the MiniMed 770G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 2 years of age or older

L. **If you are requesting the MiniMed 780G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 7 years of age or older

M. **If you are requesting the MiniMed 630G, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 14 years of age or older

N. **If you are requesting the iLet Bionic Pancreas insulin pump, approval also requires:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
   2. You are 6 years of age or older

O. **If you are requesting the MiniMed Flex starter kit (infusion pump) or the MiniMed Extended supply kit, approval also requires ONE of the following:**
   1. You have type 1 diabetes mellitus (a disorder with high blood sugar) AND are 7 years of age and older
   2. You have type 2 diabetes mellitus (a disorder with high blood sugar), are 18 years of age and older, AND require insulin

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INTERFERON ALFA-2B

Generic	Brand				
INTERFERON ALFA-2B,RECOMB.	INTRON A				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chronic hepatitis C (a type of liver infection)
   2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
   3. Condylomata acuminate (genital warts)
   4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
   5. Chronic hepatitis B (a type of liver infection)
   6. Non-Hodgkin's lymphoma (a type of blood cancer)
   7. Malignant melanoma (a type of skin cancer)
   8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cancer) who are minimally treated (within 1 year of diagnosis)
   9. Follicular lymphoma (a type of blood cancer)
   10. Angioblastoma (certain blood-vessel tumors of the brain)
   11. Carcinoid tumor (a type of slow growing cancerous tumor)
   12. Chronic myeloid leukemia (a type of blood cancer)
   13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)
   14. Multiple myeloma (a type of blood cancer)
   15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
   16. Ovarian cancer (a type of reproductive system cancer)
   17. Polycythemia vera (a type of blood cancer)
   18. Renal cell carcinoma (a type of kidney cancer)
   19. Skin cancer
   20. Thrombocytosis (your body makes too many platelets)
   21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)

(Initial criteria continued on next page)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

B. **If you have chronic hepatitis C, approval also requires:**
   1. You have genotype 1, 2, 3, 4, 5, or 6 infection (types of hepatitis C virus)
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   3. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of 50 IU/mL or higher
   4. Intron A will be used with ribavirin or you have a contraindication to (harmful for you to use) ribavirin
   5. You had a trial of or contraindication to one clinical standard of care medication: peginterferon alfa-2a or peginterferon alfa-2b

RENEWAL CRITERIA

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for renewal:

A. The request is for continuation of current therapy or renewal with Intron A therapy
B. **If you have chronic hepatitis C (type of liver infection), renewal also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
   2. If you already received 24 weeks or more of interferon treatment, your HCV (hepatitis C virus) RNA level (amount of virus in your blood) is undetectable (less than 50 IU/mL) at 24 weeks

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INTERFERON FOR MS - AVONEX

Generic	Brand				
INTERFERON BETA-1A	AVONEX, AVONEX PEN				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - AVONEX** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)

You are 18 years of age or older

Effective: 02/01/26

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INTERFERON FOR MS - BETASERON

Generic	Brand				
INTERFERON BETA-1B	BETASERON				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - BETASERON** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)

You are 18 years of age or older

Effective: 02/01/26

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INTERFERON FOR MS - EXTAVIA

Generic	Brand				
INTERFERON BETA-1B	EXTAVIA				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - EXTAVIA** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), or active secondary progressive disease (advanced disease)

You are 18 years of age or older

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Avonex (interferon beta-1a), Copaxone/Glatiramer/Glatopa (glatiramer), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a/albumin), teriflunomide (Aubagio)

Effective: 01/01/26

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INTERFERON FOR MS - PLEGRIDY

Generic	Brand				
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - PLEGRIDY** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)

You are 18 years of age or older

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INTERFERON FOR MS - REBIF

Generic	Brand				
INTERFERON BETA-1A/ALBUMIN	REBIF, REBIF REBIDOSE				

GUIDELINES FOR USE

Our guideline named **INTERFERON FOR MS - REBIF** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)

You are 18 years of age or older

Effective: 02/01/26

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INTERFERON GAMMA-1B, RECOMB

Generic	Brand				
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Chronic granulomatous disease (CGD: a type of immune disorder)
   2. Severe malignant osteopetrosis (SMO: a type of bone condition)

B. **If you have chronic granulomatous disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), infectious disease specialist (a doctor that specializes in treating infections), or immunologist (a type of immune system doctor)

C. **If you have severe malignant osteopetrosis, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor) or hematologist (a type of blood doctor)

RENEWAL CRITERIA

Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for renewal:

A. You have ONE of the following:
   1. Chronic granulomatous disease (CGD: a type of immune disorder)
   2. Severe malignant osteopetrosis (SMO: a type of bone condition)

B. You have shown clinical benefit compared to baseline (such as reduction in frequency and severity of serious infections)

C. You have NOT received hematopoietic cell transplantation (bone marrow transplant)

Effective: 01/01/25

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IOBENGUANE IODINE 131 (NSA)

Generic	Brand			
IOBENGUANE I 131	AZEDRA			

GUIDELINES FOR USE

Our guideline named **IOBENGUANE IODINE 131 (Azedra)** requires the following rule(s) be met for approval:

You have unresectable (cannot be removed completely through surgery), locally advanced or metastatic pheochromocytoma (type of tumor that releases hormones) or paraganglioma (type of tumors)

You are 12 years of age or older

You require systemic anticancer therapy (cancer treatment that travels in the blood throughout the entire body)

The tumors are iobenguane scan positive (type of test that detects a tumor)

You have **NOT** previously received 1 dosimetric dose (measurement of how much radiation dose is absorbed by the body) and 2 therapeutic doses of Azedra

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Effective: 07/01/20

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IPILIMUMAB

Generic	Brand				
IPILIMUMAB	YERVOY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
- Cutaneous melanoma (a type of skin cancer)
- Advanced renal cell carcinoma (a type of kidney cancer)
- Unresectable or metastatic colorectal cancer (type of digestive tract cancer that cannot be completely removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic hepatocellular carcinoma (a type of liver cancer that cannot be completely removed by surgery or has spread to other parts of the body)
- Metastatic or recurrent non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body or has returned)
- Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (a tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs)
- Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC: a type of digestive cancer that cannot be removed by surgery or has spread to other parts of the body)

If you have unresectable or metastatic melanoma, approval also requires:
- You are 12 years of age or older
- Yervoy will be used as a single medication OR in combination with Opdivo (nivolumab)

If you have cutaneous melanoma, approval also requires:
- Yervoy will be used for adjuvant (add-on) treatment
- There is pathologic (disease) involvement of regional lymph nodes of more than 1mm
- You have undergone complete resection (surgery to completely remove cancer), including total lymphadenectomy (lymph glands are surgically removed)

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IPILIMUMAB

INITIAL CRITERIA (CONTINUED)

If you have advanced renal cell carcinoma, approval also requires:
- Yervoy will be used in combination with Opdivo (nivolumab)
- You have intermediate or poor risk disease

If you have unresectable or metastatic colorectal cancer, approval also requires:
- You are 12 years of age or older
- Yervoy will be used in combination with Opdivo (nivolumab)
- Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires ONE of the following:
- Yervoy will be used in combination with Opdivo (nivolumab) as first-line treatment
- Yervoy will be used in combination with Opdivo (nivolumab), AND you have previously been treated with Nexavar (sorafenib)

If you have metastatic or recurrent non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (types of gene mutations)
- You meet ONE of the following:
  - **For metastatic NSCLC,** Yervoy will be used in combination with Opdivo (nivolumab) AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%), as determined by an FDA (Food and Drug Administration)-approved test
  - **For metastatic or recurrent NSCLC,** Yervoy will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)

If you have unresectable malignant pleural mesothelioma, approval also requires:
- You are 18 years of age or older
- Yervoy will be used in combination with Opdivo (nivolumab)

If you have unresectable advanced or metastatic esophageal squamous cell carcinoma, approval also requires:
- You are 18 years of age or older
- Yervoy will be used in combination with Opdivo (nivolumab)

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IPILIMUMAB

RENEWAL CRITERIA

NOTE: For the diagnoses of unresectable or metastatic melanoma, advanced renal cell carcinoma, unresectable or metastatic colorectal cancer, unresectable or metastatic hepatocellular carcinoma, metastatic/recurrent non-small cell lung cancer (NSCLC), unresectable malignant pleural mesothelioma, or unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC), please refer to the Initial Criteria section.

Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for renewal:
You have cutaneous melanoma (a type of skin cancer)
Yervoy will be used for adjuvant (add-on) treatment
You do NOT have any disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant metastasis [cancer has spread from original site])

Effective: 05/12/25

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IPTACOPAN

Generic	Brand				
IPTACOPAN HCL	FABHALTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
- Complement 3 glomerulopathy (C3G: a type of kidney disease)

If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- Your paroxysmal nocturnal hemoglobinuria (PNH) diagnosis is confirmed by flow cytometry (a type of lab test) that shows ALL of the following:
  - You have a PNH granulocyte clone size of at least 10%
  - You have at least 2 different GPI-protein deficiencies (a certain type of protein is missing, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
- You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]) or Factor D inhibitor (such as Voydeya [danicopan])

(Initial criteria continued on next page)

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IPTACOPAN

INITIAL CRITERIA (CONTINUED)

If you have primary immunoglobulin A nephropathy, approval also requires:

- You are 18 years of age or older
- You are at risk of rapid disease progression (such as a urine protein-to-creatinine ratio [UPCR: a test that measures the amount of protein in urine] of at least 1.5 g/g)
- Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
- Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
- You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 20 mL/min/1.73 m(2)
- You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

If you have complement 3 glomerulopathy, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
- Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
- You have a urine-protein creatine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1g/g
- You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30mL/min/1.73m(2)
- You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
- You will NOT use Fabhalta concurrently (at the same time) with another complement inhibitor (such as Empaveli [pegcetacoplan]) for the treatment of complement 3 glomerulopathy (a type of kidney disease)

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IPTACOPAN

RENEWAL CRITERIA

Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
- Complement 3 glomerulopathy (C3G: a type of kidney disease)

If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
- You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [type of protein in red blood cells] levels) compared to baseline (before treatment)
- You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]) or Factor D inhibitor (such as Voydeya [danicopan])

If you have primary immunoglobulin A nephropathy, renewal also requires:
- You meet ONE of the following:
  - You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
  - You have improved or stable kidney function compared to baseline (before starting Fabhalta)

If you have complement 3 glomerulopathy, renewal also requires:
- You have improved or stable kidney function compared to baseline (before treatment) OR you have a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
- You will NOT use Fabhalta concurrently (at the same time) with another complement inhibitor (such as Empaveli [pegcetacoplan]) for the treatment of complement 3 glomerulopathy (a type of kidney disease)

Effective: 01/01/26

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IRINOTECAN LIPOSOMAL (NSA)

Generic	Brand			
IRINOTECAN LIPOSOMAL	ONIVYDE			

GUIDELINES FOR USE

Our guideline named **IRINOTECAN LIPOSOMAL (Onivyde)** requires the following rule(s) be met for approval:

You have metastatic pancreatic adenocarcinoma (a type of cancer of the pancreas that has spread to other parts of the body)

You are 18 years of age or older

You meet ONE of the following:

- Onivyde will be used in combination with oxaliplatin, fluorouracil and leucovorin as first-line treatment (used for initial treatment)
- Onivyde will be used in combination with fluorouracil and leucovorin AND you have experienced disease progression (disease has worsened) following gemcitabine-based therapy (a type of cancer drug)

Effective: 03/04/24

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ISATUXIMAB-IRFC (NSA)

Generic	Brand				
ISATUXIMAB-IRFC	SARCLISA				

GUIDELINES FOR USE

Our guideline named **ISATUXIMAB-IRFC (Sarclisa)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Multiple myeloma (type of blood cancer)
- Relapsed or refractory multiple myeloma (type of blood cancer that has returned or no longer responds to treatment)

If you have multiple myeloma, approval also requires:
- You are 18 years of age or older
- Sarclisa will be used in combination with Pomalyst (pomalidomide) and dexamethasone
- You have received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (such as Ninlaro [ixazomib], Kyprolis [carfilzomib])

If you have relapsed or refractory multiple myeloma, approval also requires:
- You are 18 years of age or older
- Sarclisa will be used in combination with Kyprolis (carfilzomib) and dexamethasone
- You have received one to three prior lines of therapy

If you have newly diagnosed multiple myeloma, approval also requires:
- You are 18 years of age or older
- Sarclisa will be used in combination with Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone
- You are not eligible for autologous stem cell transplant (ASCT: a type of treatment that uses your own healthy blood cells)

Effective: 10/21/24

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ISAVUCONAZONIUM

Generic	Brand				
ISAVUCONAZONIUM SULFATE	CRESEMBA				

GUIDELINES FOR USE

Our guideline named **ISAVUCONAZONIUM (Cresemba)** requires the following rule(s) be met for approval:

You meet ONE of the following:

- This is a request for continuation of therapy after you were started on Cresemba in the hospital
- You have invasive aspergillosis (a type of fungal infection)
- You have invasive mucormycosis (a type of fungal infection)

If you have invasive aspergillosis, approval also requires:

- You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
- You have tried or have a contraindication to (harmful for you to use) voriconazole

If you have invasive mucormycosis, approval also requires:

- You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

Effective: 02/01/26

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ISTRADEFYLLINE

Generic	Brand				
ISTRADEFYLLINE	NOURIANZ				

GUIDELINES FOR USE

Our guideline named **ISTRADEFYLLINE (Nourianz)** requires the following rule(s) be met for approval:
You have Parkinson's disease (a type of movement disorder)
You are 18 years of age or older
You are experiencing 'OFF' episodes (period of symptoms in between doses)
You will use Nourianz concurrently (together) with levodopa/carbidopa(such as Sinemet, Sinemet CR [extended-release])
You have tried or have a contraindication to (harmful for you to use) TWO Parkinson's disease medications from different medication classes as follows:
Dopamine agonists (such as ropinirole, pramipexole, rotigotine)
Monoamine oxidase-inhibitors (such as selegiline, rasagiline)
Catechol-O-methyl transferase inhibitors (such as entacapone, tolcapone)

Effective: 02/01/26

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ITRACONAZOLE - TOLSURA

Generic	Brand				
ITRACONAZOLE	TOLSURA				

GUIDELINES FOR USE

Our guideline named **ITRACONAZOLE - TOLSURA** requires the following rule(s) be met for approval:

You have ONE of the following fungal infections:
- Blastomycosis (pulmonary and extrapulmonary) (a type of fungal infection affecting in and outside of the lungs)
- Histoplasmosis (a type of fungal infection) (including chronic cavitary pulmonary [affecting the lungs] disease and disseminated, nonmeningeal [not affecting spinal cord and brain membranes] histoplasmosis)
- Aspergillosis (pulmonary and extrapulmonary) (a type of fungal infection in and outside of the lungs)

If you have blastomycosis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
- You have tried a generic itraconazole formulation
- Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of medication in the body that has an effect)

If you have histoplasmosis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
- You have tried a generic itraconazole formulation
- Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of medication in the body that has an effect)

If you have aspergillosis, approval also requires:
- You are 18 years of age or older
- You are intolerant or refractory (not responsive) to amphotericin B therapy
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
- You have tried a generic itraconazole formulation
- Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of medication in the body that has an effect)

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IVACAFTOR

Generic	Brand			
IVACAFTOR	KALYDECO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 1 month of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Kalydeco)
F. You are NOT homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) in the CFTR gene

RENEWAL CRITERIA

Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You have experienced an improvement in your clinical status
C. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

Effective: 01/28/25

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IVOSIDENIB

Generic	Brand				
IVOSIDENIB	TIBSOVO				

GUIDELINES FOR USE

Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
- Myelodysplastic syndromes (MDS: a type of blood cancer)
- Cholangiocarcinoma (bile duct cancer)

If you have newly diagnosed acute myeloid leukemia (such as you are starting or previously started Tibsovo treatment at the time your condition was identified), approval also requires:
- Tibsovo will be used in combination with azacitidine (Onureg) or as monotherapy (one drug treatment)
- Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- You meet ONE of the following:
  - You are 75 years of age or older
  - You are between 18 and 74 years of age AND you have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of initial therapy to treat cancer)

If you have relapsed or refractory acute myeloid leukemia (cancer that has returned or has not responded to treatment), approval also requires:
- You are 18 years of age or older
- Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

If you have myelodysplastic syndromes, approval also requires:
- You are 18 years of age or older
- Your cancer has relapsed or is refractory (cancer that has returned or has not responded to treatment)
- Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

(Criteria continued on next page)

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

If you have cholangiocarcinoma, approval also requires:

You are 18 years of age or older

Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)

Your cancer has been previously treated

Your cancer has an isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

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Effective: 08/11/25

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IXABEPILONE (NSA)

Generic	Brand			
IXABEPILONE	IXEMPRA			

GUIDELINES FOR USE

Our guideline named **IXABEPILONE** requires the following rule(s) be met for approval:
You have metastatic (cancer that has spread to other parts of body) or locally advanced breast cancer
You meet **ONE** of the following:
You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) **OR**
You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), and a taxane (paclitaxel or docetaxel) **AND** the requested medication is being used in combination with Xeloda (capecitabine)

Effective: 07/01/20

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IXAZOMIB

Generic	Brand				
IXAZOMIB CITRATE	NINLARO				

GUIDELINES FOR USE

Our guideline named **IXAZOMIB (Ninlaro)** requires the following rule(s) be met for approval:
You have multiple myeloma (a type of blood cancer)
Ninlaro will be used in combination with Revlimid (lenalidomide) and dexamethasone
You have received at least one prior therapy (such as Velcade [bortezomib], Kyprolis [carfilzomib], Thalomid [thalidomide], Revlimid [lenalidomide], Alkeran [melphalan], stem cell transplantation [a type of procedure])

Effective: 02/01/26

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IXEKIZUMAB

Generic	Brand				
IXEKIZUMAB	TALTZ SYRINGE, TALTZ AUTOINJECTOR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Taltz
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

(Initial criteria continued on next page)

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Taltz
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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IXEKIZUMAB

RENEWAL CRITERIA

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

Effective: 07/22/26

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LACOSAMIDE

Generic	Brand				
LACOSAMIDE	MOTPOLY XR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Partial-onset seizures (a type of seizure)
- Primary generalized tonic-clonic seizures (a type of seizure)

If you have primary-onset seizures, approval also requires:
- You weigh at least 50 kilograms (110 pounds)
- You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
- You are not able to tolerate lacosamide immediate-release

If you have primary generalized tonic-clonic seizures, approval also requires:
- You weigh at least 50 kilograms (110 pounds)
- Motpoly XR will be used as adjunctive (add-on) treatment
- You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
- You are not able to tolerate lacosamide immediate-release

RENEWAL CRITERIA

Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Partial-onset seizures (a type of seizure)
- Primary generalized tonic-clonic seizures (a type of seizure)

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LACTIC ACID/CITRIC/POTASSIUM

Generic	Brand				
LACTIC ACID/CITRIC/POTASSIUM	PHEXX				

Please refer to CONTRACEPTIVE ZERO COST SHARE OVERRIDE section below if the request is also for zero copay override.

GUIDELINES FOR USE

Our guideline named **LACTIC ACID/CITRIC/POTASSIUM (Phexx)** requires the following rule(s) be met for approval:

You are a female patient with reproductive potential using the requested medication for prevention of pregnancy

You will NOT use Phexx concurrently (at the same time) with vaginal ring products (such as Annovera, Nuvaring)

You have tried or have a contraindication to (harmful for you to use) TWO preferred contraceptive medications (such as an intrauterine device [Mirena, Kyleena, Liletta, Skyla, ParaGard], hormonal implant, injection, patch, or oral products [Nexplanon, Depo-Provera, Xulane])

CONTRACEPTIVE ZERO COST SHARE OVERRIDE CRITERIA

Our guideline named **CONTRACEPTIVE ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

The request is for ONE of the following:

- A generic contraceptive agent
- A single-source brand (SSB) contraceptive agent that has no preferred generic agents or therapeutically equivalent products available
- A multi-source brand (MSB) contraceptive agent

If the request is for a single-source brand or multi-source brand contraceptive medication, approval also requires ONE of the following:

- Two preferred medications are medically inappropriate for you (or one if only one agent is available)
- You have tried or have a documented medical contraindication (harmful for) to two preferred medications (or one if only one agent is available)
- Your doctor has provided documentation confirming that the requested drug is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to the appropriate use)

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Generic	Brand				
LAMOTRIGINE	SUBVENITE				

GUIDELINES FOR USE

Our guideline named **LAMOTRIGINE (Subvenite)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Partial-onset seizures (a type of seizure)
- Primary generalized tonic-clonic (PGTC) seizures (a type of seizure)
- Generalized seizures of Lennox-Gastaut syndrome (a type of seizure disorder in young children)
- Bipolar I disorder (a type of mood disorder)

If you have partial-onset seizures, approval also requires ONE of the following:
- You will use Subvenite as adjunctive (add-on) therapy and meet ALL of the following:
  - You are 2 years of age or older
  - You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets
- You will use Subvenite as monotherapy (one medication treatment) and meet ALL of the following:
  - You are 16 years of age or older
  - You are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as a single antiepileptic medication (a type of medication used to treat epilepsy or seizures) but you will switch to Subvenite
  - You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

If you have primary generalized tonic-clonic seizures or generalized seizures, approval also requires:
- You are 2 years of age or older
- You will use Subvenite as adjunctive (add-on) therapy
- You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

If you have bipolar I disorder, approval also requires:
- You will use Subvenite for maintenance treatment
- You are receiving treatment with standard therapy (such as olanzapine, valproate, lithium) for acute mood episodes (depression, mania, hypomania, mixed episodes [types of mood disorders])
- You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

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LANADELUMAB-FLYO

Generic	Brand				
LANADELUMAB-FLYO	TAKHZYRO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 2 years of age or older
C. Takhzyro will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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LANADELUMAB-FLYO

RENEWAL CRITERIA

Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

Effective: 07/01/26

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LANREOTIDE

Generic	Brand				
LANREOTIDE ACETATE	SOMATULINE DEPOT, LANREOTIDE ACETATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LANREOTIDE (Somatuline Depot)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acromegaly (a type of hormone disorder)
- Gastroenteropancreatic neuroendocrine tumors (GEP-NETs: a rare type of tumor)
- Carcinoid syndrome (a set of symptoms caused by a type of tumor that releases substances into the body)

If you have acromegaly, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- You had an inadequate response (did not work) to or cannot be treated with surgery or radiation therapy
- Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Sandostatin LAR Depot (octreotide acetate ER)

If you have gastroenteropancreatic neuroendocrine tumors, approval also requires:
- You are 18 years of age or older
- You have unresectable (unable to remove by surgery), well or moderately differentiated, locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic (cancer that has spread to other parts of the body) gastroenteropancreatic neuroendocrine tumors (a rare type of tumor)

If you have carcinoid syndrome, approval also requires:
- You are 18 years of age or older

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LANREOTIDE

RENEWAL CRITERIA

NOTE: For the diagnoses of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) or carcinoid syndrome, please refer to the Initial Criteria section.

Our guideline named **LANREOTIDE (Somatuline Depot)** requires the following rule(s) be met for renewal:
You have acromegaly (a type of hormone disorder)
You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

Effective: 01/01/26

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LAPATINIB

Generic	Brand				
LAPATINIB DITOSYLATE	TYKERB, LAPATINIB				

GUIDELINES FOR USE

Our guideline named **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:

You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)

Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive

If you have advanced breast cancer, approval also requires:

The requested medication will be used in combination with Xeloda (capecitabine)

You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)

If you have metastatic breast cancer, approval also requires ONE of the following:

The requested medication will be used in combination with Xeloda (capecitabine), AND you have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), and a taxane (such as paclitaxel, docetaxel)

The requested medication will be used in combination with Femara (letrozole), your tumor is hormone receptor (HR: a type of protein)-positive, and you are a postmenopausal (after menopause) woman

Effective: 02/01/26

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LAROTRECTINIB

Generic	Brand			
LAROTRECTINIB	VITRAKVI			

GUIDELINES FOR USE

Our guideline named **LAROTRECTINIB (Vitrakvi)** requires the following rule(s) be met for approval:

A. You have a solid tumor (abnormal mass of tissue that usually does not contain cysts or liquid)
B. Your tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation (you have a type of enzyme that doesn't have a mutation)
C. Your tumor is metastatic (spreads to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. There are no satisfactory alternative treatments, or your tumor has gotten worse after treatment
E. **Requests for Vitrakvi oral solution also require ONE of the following:**
    1. You are a pediatric patient (less than 18 years of age)
    2. You are unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. You have other medical need for the oral solution

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LASMIDITAN

Generic	Brand				
LASMIDITAN SUCCINATE	REYVOW				

GUIDELINES FOR USE

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
The request is for acute (quick onset) treatment of migraines (a type of headache)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

RENEWAL CRITERIA

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
The request is for acute (quick onset) treatment of migraines (a type of headache)
You meet ONE of the following:
- You have experienced an improvement from baseline (before treatment) in a validated acute treatment patient-reported outcome questionnaire (such as Migraine Assessment of Current Therapy [MIGRAINE-ACT: assessment tool used to help guide treatment])
- You have experienced clinical improvement as defined by ONE of the following:
  - Ability to function normally within 2 hours of dose
  - Headache pain disappears within 2 hours of dose
  - Treatment works consistently in majority of migraine attacks

Effective: 01/01/26

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LAZERTINIB

Generic	Brand				
LAZERTINIB MESYLATE	LAZCLUZE				

GUIDELINES FOR USE

Our guideline named **LAZERTINIB (Lazcluze)** requires the following rule(s) be met for approval:

You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)

You are 18 years of age or older

Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw) or Rybrevant Faspro (amivantamab-hyaluronidase-lpuj)

Your tumor has epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

Effective: 01/19/26

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LEBRIKIZUMAB-LBKZ

Generic	Brand				
LEBRIKIZUMAB-LBKZ	EBGLYSS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
E. You meet ONE of the following:
    1. You were previously stable on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and are switching to Ebglyss
    2. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
    3. You have atopic dermatitis (a type of skin condition)affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies:
    1. Topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate)
    2. Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
    3. Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
    4. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
    5. Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
    6. Phototherapy (a type of light therapy)

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LEBRIKIZUMAB-LBKZ

RENEWAL CRITERIA

Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for renewal:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You have shown improvement while on Ebglyss
C. You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

Effective: 08/21/26

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LECANEMAB-IRMB

Generic	Brand				
LECANEMAB-IRMB	LEQEMBI, LEQEMBI IQLIK				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LECANEMAB-IRMB (Leqembi, Leqembi IQLIK)** requires the following rule(s) be met for approval:

A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
B. You are 50 years of age or older
C. You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or psychiatrist (a type of mental health doctor)
E. You had an amyloid pathology (abnormal buildup of a type protein) confirmed by positron emission tomography (PET: a type of imaging test) or detected by cerebrospinal fluid (CSF: a type of liquid in the brain and spinal cord)-based testing (such as amyloid-beta 42 [Aβ42], total tau [T-tau], phosphorylated tau [P-tau]) (types of lab tests)
F. You have a Clinical Dementia Rating (CDR: a tool for evaluating memory loss) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE: a test used to evaluate memory, thinking, and understanding) score of 20 to 28 at baseline (before treatment)
G. You have Alzheimer's Association Workgroup Clinical Stage 3 (cognitive impairment [decreased ability to process, understand, store and remember information] but mostly maintains independence on activities of daily living [ADL: basic everyday tasks]) or Clinical Stage 4 (cognitive impairment with mild functional impairments on instrumental ADLs but independence in basic ADLs) Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
H. You have had a baseline brain MRI (magnetic resonance imaging: a type of imaging lab) within one year prior to treatment
I. You had genotype testing (a type of lab test) to determine apolipoprotein E ε4 (ApoE ε4: a type of gene) status prior to initiation of treatment OR you/your caregiver have been counseled on the risk of treatment and have waived genotype testing

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

J. You are NOT at an increased risk of cerebral bleeding (such as evidence of cerebral microhemorrhages [small amount of bleeding in the brain] or macrohemorrhages [large amount of bleeding in the brain], superficial siderosis [a type of small bleeds in the brain], vasogenic edema [a type of brain swelling], aneurysms [weak bulging spot in the blood vessel] or vascular malformations [abnormal blood vessels], lacunar infarcts [brain stroke] or severe small vessel [damaged small blood vessels in the brain] or white matter disease [damaged nerve fibers in the brain] on screening magnetic resonance imaging [MRI: a type of imaging lab], uncontrolled bleeding disorder, platelet [a type of blood cell] count less than 50,000 or international normalized ratio [a blood test to check how long it takes your blood to clot] greater than 1.5)

K. You will NOT use the requested medication concurrently (at the same time) with any other anti-amyloid medication (such as Kisunla [donanemab-azbt]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

RENEWAL CRITERIA

Our guideline named **LECANEMAB-IRMB (Leqembi, Leqembi IQLIK)** requires the following rule(s) be met for renewal:

A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

B. **If the request is for the first renewal request, renewal also requires:**
   1. You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)
   2. You will NOT use the requested medication concurrently (at the same time) with any other anti-amyloid medication (such as Kisunla [donanemab-azbt]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You do NOT have evidence of amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) on a magnetic resonance imaging (MRI: a type of imaging) scan
   b. You have a magnetic resonance imaging (MRI: a type of imaging) scan showing amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleeds in the brain) and meet ALL of the following:
      i. You do NOT have severe symptoms (such as multiple amyloid-related imaging abnormalities [ARIA: abnormal differences in the brain] episodes, macrohemorrhages [large amount of bleeding in the brain], 10 or more microhemorrhages [small amount of bleeding in the brain] since the start of treatment, 3 or more superficial siderosis [a type of small bleeds in the brain] since the start of treatment, severe ARIA, need for anticoagulation [a type of treatment to thin the blood])
      ii. You have moderate amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) (with or without symptoms) and your doctor has suspended (stopped) infusions until a repeat magnetic resonance imaging (MRI: a type of imaging) scan shows amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) has resolved or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleeds in the brain) has stabilized, OR you have asymptomatic (showing no symptoms) mild ARIA with continued MRI monitoring until ARIA-E has resolved or ARIA-H has stabilized

C. **If the request is a subsequent renewal request, renewal also requires:**
   1. You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)
   2. You will NOT use the requested medication concurrently (at the same time) with any other anti-amyloid medication (such as Kisunla [donanemab-azbt]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

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L-GLUTAMINE

Generic	Brand				
GLUTAMINE (L-GLUTAMINE)	ENDARI, GLUTAMINE (L-GLUTAMINE)				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for approval:
You have sickle cell disease (a type of blood disorder)
You are 5 years of age or older
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
The patient have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: hydroxyurea
If you are 18 years of age or older, approval also requires ONE of the following:
- You had at least 2 sickle cell crises in the past year (a sickle cell crisis is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered [injected into the vein] narcotic [a class of medications used to treat pain] or parenterally administered ketorolac, the occurrence of chest syndrome, priapism [prolonged erection of penis], or splenic sequestration [sickle-shaped blood cells trapped in spleen])
- You are having sickle-cell associated symptoms (such as pain or anemia [a type of blood condition]) which are interfering with activities of daily living
- You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

RENEWAL CRITERIA

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for renewal:
You have sickle cell disease (a type of blood disorder)
You have maintained or experienced a reduction in acute (short-term) complications of sickle cell disease (such as the number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever, low oxygen level])

Effective: 03/25/26

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LEDIPASVIR/SOFOSBUVIR

Generic	Brand				
LEDIPASVIR/ SOFOSBUVIR	HARVONI, LEDIPASVIR/ SOFOSBUVIR				

GUIDELINES FOR USE

Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
You are 3 years of age or older
You have genotype 1, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
You will NOT use Harvoni concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], rosuvastatin, Olysio [simeprevir], Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Aptivus [tipranavir]/ritonavir, St. John's wort)
You will NOT use Harvoni concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
If you are treatment-naïve (no prior treatment), approval also requires ONE of the following:
- You do not have cirrhosis (liver damage and scarring)
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
- You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
- You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, AND Harvoni will be used with ribavirin
- You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:

- You do not have cirrhosis (liver damage and scarring) AND were previously treated with a peginterferon alfa-based regimen
- You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) AND were previously treated with a peginterferon alfa-based regimen
- You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
- You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
- You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
- You have decompensated cirrhosis, failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
- You have received a liver transplant, have decompensated cirrhosis, AND Harvoni will be used with ribavirin

Harvoni will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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Effective: 08/04/25

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LEFAMULIN

Generic	Brand				
LEFAMULIN ACETATE	XENLETA				

GUIDELINES FOR USE

Our guideline named **LEFAMULIN (Xenleta)** requires the following rule(s) be met for approval:
You have community-acquired bacterial pneumonia (CABP: a type of lung infection)
You are 18 years of age or older
Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
You meet ONE of the following:
- Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
- Therapy is prescribed by or in consultation with an Infectious Disease (ID) specialist (a doctor who specializes in the treatment of infections)
- Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
  - The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
  - Xenleta will work against the bacteria
- If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Effective: 10/01/25

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LENACAPAVIR - SUNLENCA

Generic	Brand				
LENACAPAVIR SODIUM	SUNLENCA				

GUIDELINES FOR USE

Our guideline named **LENACAPAVIR - SUNLENCA** requires the following rule(s) be met for approval:

You have human immunodeficiency virus type 1 (HIV-1: a type of immune system disease caused by a virus)

You are 18 years of age or older

You are treatment-experienced (previously treated)

You have a multidrug resistant (not responding to treatment) HIV-1 infection and have failed your current antiretroviral regimen (HIV treatment) due to resistance, intolerance (side effects), or safety considerations

Effective: 08/04/25

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LENALIDOMIDE

Generic	Brand				
LENALIDOMIDE	REVLIMID, LENALIDOMIDE				

GUIDELINES FOR USE

Our guideline named **LENALIDOMIDE (Revlimid)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Multiple myeloma (MM: a type of blood cancer)
- Anemia (a type of blood condition) due to a myelodysplastic syndrome (MDS: a type of blood cancer)
- Mantle cell lymphoma (MCL: a type of blood cell)
- Follicular lymphoma (FL: a type of blood cancer)
- Marginal zone lymphoma (MZL: a type of blood cancer)

If you have multiple myeloma, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as induction, consolidation, or maintenance treatment for multiple myeloma

If you have anemia due to a myelodysplastic syndrome, approval also requires:
- You are 18 years of age or older
- Your myelodysplastic syndrome is associated with a deletion 5q abnormality (a type of gene mutation)

If you have mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have relapsed or progressed (disease has returned or worsened) after two prior therapies, one of which included Velcade (bortezomib)

If you have follicular lymphoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have relapsed or refractory follicular lymphoma and meet ONE of the following:
    - The requested medication will be used in combination with Monjuvi (tafasitamab-cxix) and rituximab
    - The requested medication will be used in combination with Epkinly (epcoritamab-bysp) and rituximab
  - You have been previously treated for follicular lymphoma AND the requested medication will be used in combination with a rituximab product (a type of cancer medication)

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

If you have marginal zone lymphoma, approval also requires:
You are 18 years of age or older
You have previously been treated for marginal zone lymphoma
The requested medication will be used in combination with a rituximab product (a type of cancer medication)

Effective: 12/15/25

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LENIOLISIB

Generic	Brand				
LENIOLISIB PHOSPHATE	JOENJA				

GUIDELINES FOR USE

Our guideline named **LENIOLISIB (Joenja)** requires the following rule(s) be met for approval:
You have activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS: a type of mutation that impacts the immune system)
You are 12 years of age or older

Effective: 02/01/26

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LENVATINIB

Generic	Brand			
LENVATINIB MESYLATE	LENVIMA			

GUIDELINES FOR USE

Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following:
   1. Differentiated thyroid cancer (DTC: a type of thyroid cancer)
   2. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)
   4. Advanced endometrial carcinoma (EC: a type of uterus cancer)

B. **If you have differentiated thyroid cancer, approval also requires:**
   1. Your thyroid cancer is locally recurrent (re-appears in the same spot) or metastatic (has spread to other parts of the body)
   2. Your thyroid cancer is progressive (getting worse)
   3. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy

C. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Lenvima will be used in combination with pembrolizumab (Keytruda)
      b. Lenvima will be used in combination with everolimus (Afinitor) AND you have tried one anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. **If you have hepatocellular carcinoma, approval also requires:**
   1. Your cancer is unresectable (cannot be removed by surgery)

E. **If you have advanced endometrial carcinoma, approval also requires:**
   1. Lenvima will be used in combination with pembrolizumab (Keytruda)
   2. Your cancer is mismatch repair proficient (pMMR: your tumor has normal expression of types of protein) OR is not microsatellite instability-high (MSI-H: a type of mutation), as determined by a Food and Drug Administration (FDA)-approved test
   3. You have experienced disease progression (worsening) following prior systemic therapy (treatment that targets the entire body)
   4. You are not a candidate for curative (to cure) surgery or radiation

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LETERMOVIR

Generic	Brand				
LETERMOVIR	PREVYMIS				

GUIDELINES FOR USE

Our guideline named **LETERMOVIR (Prevymis)** requires the following rule(s) be met for approval:

The request is for ONE of the following:
- Prophylaxis (prevention) of cytomegalovirus (CMV: a type of virus) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT: cells transplanted from a matching donor) recipient
- Prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient

If the request is for prophylaxis of cytomegalovirus infection and disease in an allogeneic hematopoietic stem cell transplant recipient, approval also requires:
- You are 6 months of age or older
- Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist (a doctor who specializes in the treatment of infections)
- You are a CMV-seropositive recipient [R+] of an allogeneic HSCT
- You will start or have started Prevymis between Day 0 and Day 28 post (after)-transplant (before or after engraftment [a type of transplant])
- You meet ONE of the following:
  - You are NOT at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 100 days post (after)-transplant
  - You are at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 200 days post (after)-transplant

If the request is for prophylaxis of cytomegalovirus disease in a kidney transplant recipient, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist (a doctor who specializes in the treatment of infections)
- You are a kidney transplant recipient at high risk (donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
- You will start or have started Prevymis between Day 0 and Day 7 post (after)-transplant
- You will not receive Prevymis beyond 200 days post (after)-transplant

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LEUPROLIDE

Generic	Brand				
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEUPROLIDE** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   3. Central precocious puberty (CPP: early sexual development in girls and boys)

B. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. **If you are female and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 8 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

(Initial criteria continued on next page)

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LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

RENEWAL CRITERIA

NOTE: For the diagnosis of advanced prostate cancer, please refer to the Initial Criteria section.

Our guideline named **LEUPROLIDE** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. **If you have central precocious puberty, renewal also requires:**
   1. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   2. You have NOT reached the actual age which corresponds to your current pubertal age

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LEUPROLIDE DEPOT (NSA)

Generic	Brand				
LEUPROLIDE ACETATE	LEUPROLIDE DEPOT, LUTRATE DEPOT				

GUIDELINES FOR USE

Our guideline named **LEUPROLIDE DEPOT** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

B. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

Effective: 07/01/26

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LEUPROLIDE-ELIGARD

Generic	Brand				
LEUPROLIDE ACETATE	ELIGARD				

GUIDELINES FOR USE

Our guideline named **LEUPROLIDE-ELIGARD** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

B. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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LEUPROLIDE-FENSOLVI (NSA)

Generic	Brand				
LEUPROLIDE ACETATE	FENSOLVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEUPROLIDE-FENSOLVI** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. **If you are female and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 8 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

(Initial criteria continued on next page)

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LEUPROLIDE-FENSOLVI (NSA)

INITIAL CRITERIA (CONTINUED)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

RENEWAL CRITERIA

Our guideline named **LEUPROLIDE-FENSOLVI** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. **If you have central precocious puberty, renewal also requires:**
   1. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   2. You have NOT reached the actual age which corresponds to your current pubertal age

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LEUPROLIDE-LUPRON DEPOT (NSA)

Generic	Brand				
LEUPROLIDE ACETATE	LUPRON DEPOT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEUPROLIDE-LUPRON DEPOT** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
Moderate to severe pain from endometriosis (condition affecting the uterus)
Uterine leiomyomata (fibroids: noncancerous growths in the uterus)
If you have gender dysphoria, approval also requires:
Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved
If you have moderate to severe pain from endometriosis, approval also requires:
Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
You had a trial of or contraindication (harmful for) to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
Lupron Depot will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)
You have NOT received more than 12 months of treatment with Lupron Depot per lifetime
If you have uterine leiomyomata (fibroids), approval also requires:
Lupron Depot will be used with iron therapy for the preoperative (before surgery) hematologic (blood) improvement of anemia (a type of blood condition) caused by fibroids
Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
You will NOT use Lupron Depot concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Oriahnn [elagolix/estradiol/norethindrone], Myfembree [relugolix/estradiol/norethindrone])

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LEUPROLIDE-LUPRON DEPOT (NSA)

RENEWAL CRITERIA

NOTE: For the diagnoses of advanced prostate cancer or uterine leiomyomata (fibroids), please refer to the Initial Criteria section.

Our guideline named **LEUPROLIDE-LUPRON DEPOT** requires the following rule(s) be met for renewal:
You have ONE of the following:
Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
Moderate to severe pain from endometriosis (condition affecting the uterus)
If you have gender dysphoria, renewal also requires:
Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved
If you have moderate to severe pain from endometriosis, renewal also requires:
You experienced improvement of pain related to endometriosis while on therapy
You are receiving add-back therapy (combination estrogen-progestin or progestin-only contraceptive preparation) at the same time
Lupron Depot will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)
You have NOT received a total of 12 months of treatment with Lupron Depot per lifetime

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LEUPROLIDE-LUPRON DEPOT-PED (NSA)

Generic	Brand				
LEUPROLIDE ACETATE	LUPRON DEPOT–PED				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEUPROLIDE-LUPRON DEPOT-PED** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. **If you are female and have central precocious puberty, approval also requires:**
   1. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   2. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   3. You are/were younger than 8 years of age when your condition started
   4. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   2. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   3. You are/were younger than 9 years of age when your condition started
   4. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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LEUPROLIDE-LUPRON DEPOT-PED (NSA)

RENEWAL CRITERIA

Our guideline named **LEUPROLIDE-LUPRON DEPOT-PED** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. **If you have central precocious puberty, renewal also requires:**
   1. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   2. You have NOT reached the actual age which corresponds to your current pubertal age

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LEUPROLIDE MESYLATE (NSA)

Generic	Brand				
LEUPROLIDE MESYLATE	CAMCEVI				

GUIDELINES FOR USE

Our guideline named **LEUPROLIDE MESYLATE (Camcevi)** requires the following rule(s) be met for approval:
You have advanced prostate cancer (a type of cancer that has spread outside of the prostate gland)
You are 18 years of age or older

Effective: 10/01/22

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LEUPROLIDE-NORETHINDRONE (NSA)

Generic	Brand				
LEUPROLIDE/ NORETHINDRONE ACET	LUPANETA PACK				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEUPROLIDE- NORETHINDRONE (Lupaneta)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:

- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
- Moderate to severe pain from endometriosis (condition affecting the uterus)

If you have moderate to severe pain from endometriosis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
- Your diagnosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
- You had a trial of or contraindication (harmful for) to a nonsteroidal anti-inflammatory drug (NSAID: such as ibuprofen, meloxicam, naproxen) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
- Lupaneta will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)
- You have NOT received more than 12 months of treatment with Lupaneta per lifetime

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LEUPROLIDE- NORETHINDRONE (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For gender dysphoria, please refer to the Initial Criteria section.

Our guideline named **LEUPROLIDE- NORETHINDRONE (Lupaneta)** requires the following rule(s) be met for renewal:
You have moderate to severe pain from endometriosis (condition affecting the uterus)
You experienced improvement of pain related to endometriosis while on therapy
You are receiving add-back therapy (combination estrogen-progestin or progestin-only contraceptive preparation) at the same time
You have NOT received a total of 12 months of treatment with Lupaneta per lifetime
Lupaneta will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)

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LEVACETYLLEUCINE

Generic	Brand				
LEVACETYLLEUCINE	AQNEURSA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for approval:

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)

RENEWAL CRITERIA

Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for renewal:

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You have shown disease improvement or a reduction in disease progression

Effective: 10/14/24

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LEVAMLODIPINE

Generic	Brand				
LEVAMLODIPINE MALEATE	CONJUPRI, LEVAMLODIPINE MALEATE				

GUIDELINES FOR USE

Our guideline named **LEVAMLODIPINE (Conjupri)** requires the following rule(s) be met for approval:
You have hypertension (high blood pressure)
You are 6 years of age or older
You have tried or have a contraindication to (harmful for you to use) TWO preferred generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine)
You have tried or have a contraindication to (harmful for you to use) TWO other preferred antihypertensive medications in another class (such as hydrochlorothiazide, lisinopril, losartan)

Effective: 03/25/26

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LEVODOPA

Generic	Brand			
LEVODOPA	INBRIJA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:

H. You have Parkinson's disease (a nerve system disorder that affects movement)
I. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
J. You are currently being treated with carbidopa/levodopa
K. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
L. You are **NOT** currently taking more than 1600mg of levodopa per day
M. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A_{2A} (such as istradefylline)

RENEWAL CRITERIA

Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:

C. You have Parkinson's disease (a nerve system disorder that affects movement)
D. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

Effective: 07/01/20

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LEVOKETOCONAZOLE

Generic	Brand				
LEVOKETOCONAZOLE	RECORLEV				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for approval:
You have Cushing's syndrome (a type of hormone disorder)
You are 18 years of age or older
You are not a candidate for surgery or surgery has not been curative (to cure)
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
You have tried or have a contraindication to (harmful for you to use) oral ketoconazole

RENEWAL CRITERIA

Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for renewal:
You have Cushing's syndrome (a type of hormone disorder)
You continue to have improvement of Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
You continue to tolerate treatment with Recorlev

Effective: 02/01/26

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LEVOTHYROXINE-ERMEZA

Generic	Brand				
LEVOTHYROXINE SODIUM	ERMEZA				

GUIDELINES FOR USE

Our guideline named **LEVOTHYROXINE-ERMEZA** requires the following rule(s) be met for approval:

You have ONE of the following:

- Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
- Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

If you have congenital or acquired hypothyroidism, approval also requires:

- You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:

- Ermeza will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
- You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

Effective: 04/01/26

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LEVOTHYROXINE-THYQUIDITY

Generic	Brand				
LEVOTHYROXINE SODIUM	THYQUIDITY				

GUIDELINES FOR USE

Our guideline named **LEVOTHYROXINE-THYQUIDITY** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

B. **If you have congenital or acquired hypothyroidism, approval also requires:**
   1. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

C. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
   1. Thyquidity will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
   2. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

Effective: 07/01/26

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LEVOTHYROXINE-TIROSINT-SOL

Generic	Brand				
LEVOTHYROXINE SODIUM	TIROSINT-SOL				

GUIDELINES FOR USE

Our guideline named **LEVOTHYROXINE-TIROSINT-SOL** requires the following rule(s) be met for approval:

You have ONE of the following:
- Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
- Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

If you have congenital or acquired hypothyroidism, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:
- Tirosint-Sol will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
- You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

Effective: 04/01/26

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LIFILEUCEL (NSA)

Generic	Brand				
LIFILEUCEL	AMTAGVI				

GUIDELINES FOR USE

Our guideline named **LIFILEUCEL (Amtagvi)** requires the following rule(s) be met for approval:
You have unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
You are 18 years of age or older
You had previous treatment with a PD-1 blocking antibody (such as Opdivo [nivolumab], Keytruda [pembrolizumab])
You have not had a previous dose of Amtagvi in your lifetime
If you have a BRAF V600 mutation positive melanoma, approval also requires you had previous treatment with a BRAF inhibitor (such as Tafinlar [dabrafenib], Zelboraf [vemurafenib], Braftovi [encorafenib])

Effective: 03/04/24

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LINVOSELTAMAB-GCPT

Generic	Brand				
LINVOSELTAMAB-GCPT	LYNOZYFIC				

GUIDELINES FOR USE

Our guideline named **LINVOSELTAMAB-GCPT (Lynozyfic)** requires the following rule(s) be met for approval:

You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)

You are 18 years of age or older

You have received at least FOUR prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody [such as Darzalex [daratumumab])

Effective: 08/04/25

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LIRAGLUTIDE - SAXENDA

Generic	Brand				
LIRAGLUTIDE	SAXENDA, LIRAGLUTIDE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LIRAGLUTIDE - SAXENDA** requires the following rule(s) be met for approval:
The request is for weight loss or weight management
You are 12 years of age or older
You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
You will NOT use Saxenda concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
If you are 18 years of age or older, approval also requires ONE of the following before starting weight loss therapy:
You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

(Initial criteria continued on next page)

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LIRAGLUTIDE - SAXENDA

INITIAL CRITERIA (CONTINUED)

If you are 12 to 17 years of age, approval also requires:
- You have a body weight greater than 60 kilograms (132 pounds)
- You have an initial body mass index (BMI: a tool for evaluating body fat) corresponding to 30 kg/m(2) for adults

RENEWAL CRITERIA

Our guideline named **LIRAGLUTIDE - SAXENDA** requires the following rule(s) be met for renewal:

The request is for weight loss or weight management

You are 12 years of age or older

You will NOT use Saxenda concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

If you are 12 to 17 years of age, approval also requires:
- You have achieved or maintained at least a 1% weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after at least 12 weeks of treatment on your maximally tolerated dose

If you are 18 years of age or older, approval also requires:
- You meet ONE of the following before starting weight loss therapy:
  - You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
  - You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
  - You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

You have achieved or maintained at least a 5% weight loss of baseline body weight after 16 weeks of treatment

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LISDEXAMFETAMINE SOLUTION

Generic	Brand				
LISDEXAMFETAMINE DIMESYLATE	ARYNTA				

GUIDELINES FOR USE

Our guideline named **LISDEXAMFETAMINE SOLUTION (Arynta)** requires the following rule(s) be met for approval:
You have ONE of the following:
Attention deficit hyperactivity disorder (ADHD: a type of mental health disorder)
Moderate to severe binge eating disorder (a type of eating disorder)
You have a contraindication to (harmful for you to use) or are unable to swallow lisdexamfetamine capsules or chewable tablets

Effective: 03/28/26

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LISINOPRIL

Generic	Brand				
LISINOPRIL	QBRELIS				

GUIDELINES FOR USE

Our guideline named **LISINOPRIL (Qbrelis)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hypertension (high blood pressure)
- Heart failure (a type of heart condition)
- Acute myocardial infarction (heart attack)

If you have hypertension, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

If you have heart failure, approval also requires:
- Qbrelis will be used as adjunct (add-on) therapy
- You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

If you have acute myocardial infarction, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

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LIXISENATIDE

Generic	Brand				
LIXISENATIDE	ADLYXIN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
You have type 2 diabetes (a disorder with high blood sugar)
You are 18 years of age or older
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
You have tried metformin (immediate-release/extended-release), a sulfonylurea (such as glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above medications (such as glipizide-metformin, pioglitazone-metformin)
You have tried a preferred GLP-1 agonist (such as Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])
You will NOT use Adlyxin concurrently (at the same time) with a DPP-4 (dipeptidyl peptidase-4) inhibitor (such as Januvia [sitagliptin], Nesina [alogliptin], Onglyza [saxagliptin])

RENEWAL CRITERIA

Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
You have type 2 diabetes (a disorder with high blood sugar)
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
You will NOT use Adlyxin concurrently (at the same time) with a DPP-4 (dipeptidyl peptidase-4) inhibitor (such as Januvia [sitagliptin], Nesina [alogliptin], Onglyza [saxagliptin])

Effective: 02/01/26

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LOFEXIDINE

Generic	Brand			
LOFEXIDINE HCL	LUCEMYRA, LOFEXIDINE HCL			

GUIDELINES FOR USE

Our guideline name **LOFEXIDINE (Lucemyra)** requires the following rule(s) be met for approval:

A. Lucemyra will be used to reduce opioid withdrawal symptoms to help abrupt opioid discontinuation
B. You are 18 years of age or older
C. You are in a setting with close monitoring of Lucemyra (lofexidine) treatment and will be treated with Lucemyra (lofexidine) for a maximum of 18 days
D. Lucemyra will be used as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (such as stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

Effective: 01/01/25

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LOMITAPIDE

Generic	Brand				
LOMITAPIDE MESYLATE	JUXTAPID				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for approval:
You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
Your diagnosis is determined by meeting ONE of the following:
- You have Simon Broome diagnostic criteria (definite) (a tool for diagnosing homozygous familial hypercholesterolemia)
- You have a Dutch Lipid Network (a tool for diagnosing homozygous familial hypercholesterolemia) criteria with a score of at least 8
- You have a clinical diagnosis based on a history of an untreated low density lipoprotein - cholesterol (LDL-C: bad cholesterol) level greater than 500 mg/dL AND you have either xanthoma (a type of skin condition) before 10 years of age or there is evidence of heterozygous familial hypercholesterolemia (HeFH: type of inherited high cholesterol) in both parents

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), endocrinologist (a type of hormone doctor), or lipidologist (a type of cholesterol doctor)
You have a low density lipoprotein cholesterol (LDL-C: bad cholesterol) level of at least 70 mg/dL while on maximally tolerated statin (medication used for cholesterol) treatment
You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: Zetia (ezetimibe)
You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Repatha (evolocumab)
- You do NOT have functional LDL (low-density lipoprotein) receptors

If you are statin tolerant, approval also requires:
- You meet ONE of the following:
  - You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
  - You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), but you are currently taking a maximally tolerated dose of any statin
- You will continue statin (medication used for cholesterol) treatment in combination with Juxtapid

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LOMITAPIDE

INITIAL CRITERIA (CONTINUED)

If you are statin intolerant, approval also requires ONE of the following:

- You have an absolute contraindication to (harmful for you to use) statin therapy (medication used for cholesterol) (such as active decompensated liver disease [symptoms related to liver damage], nursing [breastfeeding] female, pregnancy or plans to become pregnant, hypersensitivity [allergic] reaction)
- You have complete statin (medication used for cholesterol) intolerance (defined by severe and intolerable adverse effects) that have occurred with trials of at least TWO separate statins, AND the adverse effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation at least 10 times the upper limit of normal, liver function test elevation at least 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for renewal:

You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)

Your low-density lipoprotein-cholesterol (LDL-C: bad cholesterol) level has decreased while on Juxtapid

You meet ONE of the following:

- You have continued to take a maximally tolerated dose of ANY statin (medication used for cholesterol) along with Juxtapid
- You have an absolute contraindication to (harmful for you to use) statin (medication used for cholesterol) therapy
- You have complete statin (medication used for cholesterol) intolerance (severe and intolerable adverse effects)

Effective: 03/28/26

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LOMUSTINE

Generic	Brand				
LOMUSTINE	GLEOSTINE, LOMUSTINE				

GUIDELINES FOR USE

Our guideline named **LOMUSTINE (Gleostine)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Hodgkin's lymphoma (a type of blood cancer)
- Primary and metastatic brain tumors (cancer that has spread to other parts of the body)

If you have primary and metastatic brain tumors, approval also requires:

- You have previously received appropriate surgical and/or radiotherapeutic procedures
- The requested medication will be used as a part of the PCV (procarbazine, lomustine, and vincristine) regimen

Effective: 12/08/25

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LONAFARNIB

Generic	Brand				
LONAFARNIB	ZOKINVY				

GUIDELINES FOR USE

Our guideline named **LONAFARNIB (Zokinvy)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Hutchinson-Gilford Progeria Syndrome (HGPS: a rare genetic disorder)
- Processing-deficient Progeroid Laminopathies (a rare genetic disorder)

If you have Hutchinson-Gilford Progeria Syndrome, approval also requires:
- You are 1 year of age or older
- You have a body surface area (BSA) of at least 0.39 meters squared

If you have processing-deficient Progeroid Laminopathies, approval also requires:
- You are 1 year of age or older
- You have a body surface area (BSA) of at least 0.39 meters squared
- You have a heterozygous LMNA mutation (abnormal change in a type of gene) with progerin-like protein accumulation, OR you have homozygous or compound heterozygous ZMPSTE24 mutations (abnormal changes in a type of gene)

Effective: 02/01/26

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LONAPEGSOMATROPIN-TCGD

Generic	Brand				
LONAPEGSOMATROPIN-TCGD	SKYTROFA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:
You meet ONE of the following:
- You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
- You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
- You are 1 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed, as confirmed by a radiograph (type of imaging test) of the wrist and hand
- You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)
- You meet ONE of the following:
  - Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) for your age and gender

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

If you are an adult patient with growth hormone deficiency, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- You meet ONE of the following:
  - Your diagnosis is caused by a congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
  - Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests (tests that measure the body's ability to produce growth hormone):
    - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
    - Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
    - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
- You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)

Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:

You meet ONE of the following:
- You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
- You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
- You are 1 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed, as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
- You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)
- You meet ONE of the following:
  - Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity (rate of growth) is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty

If you are an adult patient with growth hormone deficiency, renewal also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (type of hormone doctor)
- You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)
- You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)

Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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LONCASTUXIMAB TESIRINE-LPYL (NSA)

Generic	Brand				
LONCASTUXIMAB TESIRINE-LPYL	ZYNLONTA				

GUIDELINES FOR USE

Our guideline named **LONCASTUXIMAB TESIRINE-LPYL (Zynlonta)** requires the following rule(s) be met for approval:

You have relapsed or refractory large B-cell lymphoma (type of white blood cell cancer that has returned or is not responding to treatment), including diffuse large B-cell lymphoma (DLBCL), DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma

You are 18 years of age or older

You previously received two or more lines of systemic therapy (treatment that travels throughout the body)

Effective: 10/01/21

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LORLATINIB

Generic	Brand				
LORLATINIB	LORBRENA				

GUIDELINES FOR USE

Our guideline named **LORLATINIB (Lorbrena)** requires the following rule(s) be met for approval:

You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)

You are 18 years of age or older

Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive, as detected by a Food and Drug Administration (FDA)-approved test

You have tried or have a contraindication to (harmful for you to use) ONE of the following first-line preferred medications: Alecensa (alectinib), Alunbrig (brigatinib)

Effective: 04/01/26

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LOSARTAN

Generic	Brand				
LOSARTAN POTASSIUM	ARBLI				

GUIDELINES FOR USE

Our guideline named **LOSARTAN (Arbli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hypertension (high blood pressure)
   2. Hypertension with left ventricular hypertrophy (a type of heart condition)
   3. Type 2 diabetes (a disorder with high blood sugar) with diabetic nephropathy (a type of kidney disease caused by high blood sugar)

B. **If you have hypertension, approval also requires:**
   1. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

C. **If you have hypertension with left ventricular hypertrophy, approval also requires:**
   1. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

D. **If you have type 2 diabetes with diabetic nephropathy, approval also requires:**
   1. You have a history of hypertension (high blood pressure)
   2. You have an elevated serum creatinine (a type of lab test to measure kidney function) level and proteinuria (a condition with high levels of protein in the urine) (urinary albumin to creatinine ratio of at least 300mg/g)
   3. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

Effective: 07/01/25

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LOTILANER

Generic	Brand				
LOTILANER	XDEMVY				

GUIDELINES FOR USE

Our guideline named **LOTILANER (Xdemvy)** requires the following rule(s) be met for approval:
A. You have Demodex blepharitis (a type of inflammatory eye condition)
B. You are 18 years of age or older

Effective: 01/01/25

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LU-177 VIPIVOTIDE TETRAXETAN

Generic	Brand				
LU-177 VIPIVOTIDE TETRAXETAN	PLUVICTO				

GUIDELINES FOR USE

Our guideline named **LU-177 VIPIVOTIDE TETRAXETAN (Pluvicto)** requires the following rule(s) be met for approval:

You have metastatic castration-resistant prostate cancer (mCRPC: a type of prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

You are 18 years of age or older

Your cancer is prostate-specific membrane antigen (PSMA)-positive (a type of test)

You have been treated with androgen receptor pathway inhibitor (ARPI) therapy (such as enzalutamide, abiraterone)

You meet ONE of the following:

- It is appropriate to delay taxane-based chemotherapy (medications used to treat cancer such as docetaxel, cabazitaxel)
- You have received prior taxane-based chemotherapy

Effective: 05/05/25

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LUMACAFTOR/IVACAFTOR

Generic	Brand			
LUMACAFTOR/IVACAFTOR	ORKAMBI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 1 year of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You are homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) in the CFTR gene

RENEWAL CRITERIA

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You have experienced an improvement in your clinical status
C. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

Effective: 02/10/25

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LUMASIRAN (NSA)

Generic	Brand				
LUMASIRAN SODIUM	OXLUMO				

GUIDELINES FOR USE

Our guideline named **LUMASIRAN (Oxlumo)** requires the following rule(s) be met for approval:
You have primary hyperoxaluria type 1 (PH1: a rare disorder in which buildup of a substance called oxalate is deposited in the kidneys and urinary tract)

Effective: 04/01/21

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LURBINECTEDIN

Generic	Brand				
LURBINECTEDIN	ZEPZELCA				

GUIDELINES FOR USE

Our guideline named **LURBINECTEDIN (Zepzelca)** requires the following rule(s) be met for approval:
You have small cell lung cancer (SCLC: a type of lung cancer)
You are 18 years of age or older
You meet ONE of the following:
- You have extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer); Zepzelca will be used in combination with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs); AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide
- Your cancer is metastatic (has spread to other parts of the body); AND you had disease progression (worsening) on or after platinum-based chemotherapy (a type of cancer treatment such as carboplatin or cisplatin)

Effective: 11/03/25

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LUSPATERCEPT-AAMT

Generic	Brand				
LUSPATERCEPT-AAMT	REBLOZYL				

GUIDELINES FOR USE

Our guideline named **LUSPATERCEPT-AAMT (Reblozyl)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Beta thalassemia (a type of blood condition)
- Very low- to intermediate-risk myelodysplastic syndrome (MDS: a type of blood cancer)
- Very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS: a type of blood cancer)
- Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T: a type of blood cancer)

If you have beta thalassemia, approval also requires:
- You are 18 years of age or older
- You require regular red blood cell (RBC) transfusions (adding blood to your body)
- Reblozyl will be used for the treatment of anemia (a type of blood condition)

If you have very low- to intermediate-risk myelodysplastic syndrome, approval also requires:
- You are 18 years of age or older
- You are erythropoiesis stimulating agent (ESA)-naïve (you have not previously used a type of medication that increases the production of red blood cells such as Epogen [epoetin alfa])
- Reblozyl will be used for the treatment of anemia (a type of blood condition)

If you have very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts OR with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis, approval also requires:
- You are 18 years of age or older
- You are failing an erythropoiesis stimulating agent (ESA: a type of medication that increases the production of red blood cells, such as Epogen [epoetin alfa])
- You require at least 2 red blood cell (RBC) units over 8 weeks
- Reblozyl will be used for the treatment of anemia (a type of blood condition)

Effective: 01/19/26

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LUSUTROMBOPAG

Generic	Brand				
LUSUTROMBOPAG	MULPLETA				

GUIDELINES FOR USE

Our guideline named **LUSUTROMBOPAG (Mulpleta)** requires the following rule(s) be met for approval:
You have thrombocytopenia (a type of blood disorder)
You are 18 years of age or older
You have chronic (long-term) liver disease
You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (a type of doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), endocrinologist (a type of hormone doctor), or surgeon
You have a platelet count of less than 50x10^9 cells/L measured within the last 30 days
You will NOT use Mulpleta concurrently (at the same time) with other thrombopoietin receptor agonists [TPO-RAs] (such as Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag])

Effective: 02/01/26

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LU 177 DOTATATE (NSA)

Generic	Brand			
LUTETIUM LU 177 DOTATATE	LUTATHERA			

GUIDELINES FOR USE

Our guideline named **LUTETIUM LU 177 DOTATATE (Lutathera)** requires the following rule(s) be met for approval:

You have somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs: type of hormone cancer in digestive tract), which includes foregut, midgut, or hindgut neuroendocrine tumors

You are 12 years of age or older

Lutathera will be used together with a long-acting octreotide (such as Sandostatin LAR Depot [octreotide]) as maintenance therapy

You have previously been treated with a long-acting somatostatin analog (such as octreotide, lanreotide) before the request for Lutathera

You have NOT received a total of 4 doses of Lutathera in your lifetime

Effective: 05/17/24

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MACITENTAN

Generic	Brand				
MACITENTAN	OPSUMIT, MACITENTAN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Effective: 06/06/26

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MACITENTAN-TADALAFIL

Generic	Brand				
MACITENTAN/ TADALAFIL	OPSYNVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age or older
C. You have WHO Functional Class II-III symptoms (a way to classify how limited physical activity)
D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
E. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
F. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
G. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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MACITENTAN-TADALAFIL

RENEWAL CRITERIA

Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
B. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
C. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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MARALIXIBAT

Generic	Brand				
MARALIXIBAT CHLORIDE	LIVMARLI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

B. **If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:**
   1. You are 3 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

C. **If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:**
   1. You are 12 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

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MARALIXIBAT

RENEWAL CRITERIA

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

B. **If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)
   2. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

C. **If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)
   2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

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MARGETUXIMAB-CMKB (NSA)

Generic	Brand				
MARGETUXIMAB-CMKB	MARGENZA				

GUIDELINES FOR USE

Our guideline named **MARGETUXIMAB-CMKB (Margenza)** requires the following rule(s) be met for approval:

You have metastatic (cancer has spread to other parts of the body) HER2 (human epidermal growth factor receptor 2: type of protein found in breast cancer)-positive breast cancer

You are 18 years of age or older

Margenza will be used in combination with chemotherapy (such as Xeloda, Halaven, gemcitabine, Navelbine)

You have received two or more prior anti-HER2 regimens (such as Herceptin, Perjeta), at least one of which was for metastatic disease

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Effective: 07/01/21

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MARIBAVIR

Generic	Brand				
MARIBAVIR	LIVTENCITY				

GUIDELINES FOR USE

Our guideline named **MARIBAVIR (Livtencity)** requires the following rule(s) be met for approval:
You have a post-transplant cytomegalovirus (CMV) infection (a type of viral infection)
You are 12 years of age or older
Your infection is refractory (has not responded) to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet
Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist (a doctor who specializes in the treatment of infections)

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MARSTACIMAB-HNCQ

Generic	Brand				
MARSTACIMAB-HNCQ	HYMPAVZI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

B. **If you have hemophilia A (congenital factor VIII deficiency), approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   4. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

C. **If you have hemophilia B (congenital factor IX deficiency), approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   4. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

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MARSTACIMAB-HNCQ

RENEWAL CRITERIA

Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

B. **If you have hemophilia A (congenital factor VIII deficiency), renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (before starting Hympavzi)
   2. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

C. **If you have hemophilia B (congenital factor IX deficiency), renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (before starting Hympavzi)
   2. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

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MAVACAMTEN

Generic	Brand				
MAVACAMTEN	CAMZYOS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for approval:

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
D. You have New York Heart Association (NYHA) functional class II or III (a way to classify the severity of symptoms)
E. You have a peak left ventricular outflow tract (LVOT) gradient (evaluates the severity of disease) of at least 50 mmHg at rest or with provocation (a type of technique to evaluate how the heart performs under stress)
F. You will NOT use Camzyos concurrently (at the same time) with another myosin inhibitor (such as Myqorzo [aficamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)
G. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a beta-blocker (such as metoprolol, carvedilol), a non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem)

RENEWAL CRITERIA

Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for renewal:

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You have experienced continued clinical benefit (such as reduction of symptoms, New York Heart Association [NYHA] classification [a way to classify severity of symptoms] improvement)
C. You will NOT use Camzyos concurrently (at the same time) with another myosin inhibitor (such as Myqorzo [aficamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)

Effective:07/01/26

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MAVORIXAFOR

Generic	Brand				
MAVORIXAFOR	XOLREMDI				

GUIDELINES FOR USE

Our guideline named **MAVORIXAFOR (Xolremdi)** requires the following rule(s) be met for approval:

A. You have WHIM (warts, hypogammaglobulinemia [low levels of antibodies in the blood], infections, and myelokathexis [low white blood cell count]) syndrome (a rare genetic disorder of the immune system)
B. You are 12 years of age or older

Effective: 05/27/24

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MEBENDAZOLE

Generic	Brand			
MEBENDAZOLE	EMVERM			

GUIDELINES FOR USE

Our guideline named **MEBENDAZOLE (Emverm)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. *Enterobius vermicularis* (pinworm) infection
   2. *Trichuris trichiura* (whipworm) infection
   3. *Ascaris lumbricoides* (roundworm) infection
   4. *Ancylostoma duodenale* (hookworm) infection
   5. *Necator americanus* (hookworm) infection

B. **If you have *Enterobius vermicularis* (pinworm) infection, approval also requires:**
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) over-the-counter (OTC) pyrantel pamoate

C. **If you have Trichuris trichiura (whipworm) or Ascaris lumbricoides (roundworm) infection, approval also requires:**
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza)

D. **If you have Ancylostoma duodenale (hookworm) or Necator americanus (hookworm) infection, approval also requires:**
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza) OR over-the-counter (OTC) pyrantel pamoate

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MECAMYLAMINE

Generic	Brand				
MECAMYLAMINE HCL	VECAMYL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MECAMYLAMINE (Vecamyl)** requires the following rule(s) be met for approval:

You have moderately severe to severe essential (primary) hypertension (high blood pressure) or uncomplicated malignant hypertension (severe high blood pressure)

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)

Your blood pressure is NOT controlled on at least three anti-hypertensive medications (medications used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine], a diuretic [such as hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks

You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (high blood pressure that is caused by another medical condition) (except sleep apnea [a type of sleep condition with difficulty breathing])

You will use Vecamyl concurrently (at the same time) with at least three other anti-hypertensive medications (medications used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

You have tried or have a contraindication to (harmful for you to use) BOTH clinical standard of care medications: a potent diuretic (chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (spironolactone or eplerenone)

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MECAMYLAMINE

RENEWAL CRITERIA

Our guideline named **MECAMYLAMINE (Vecamyl)** requires the following rule(s) be met for renewal:

You have moderately severe to severe essential (primary) hypertension (high blood pressure) or uncomplicated malignant hypertension (severe high blood pressure)

You continue to benefit from Vecamyl

You will use Vecamyl concurrently (at the same time) with at least three other anti-hypertensive medications (medications used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

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Effective: 03/25/26

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MECASERMIN

Generic	Brand				
MECASERMIN	INCRELEX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Severe primary insulin-like growth factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
- Growth hormone gene deletion (not growth hormone-deficient short stature) with neutralizing antibodies to growth hormone

You are 2 years to less than 18 years of age

Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor) or nephrologist (a type of kidney doctor)

You have a height standard deviation score of less than or equal to -3.0

You have a basal IGF-1 (insulin-like growth factor 1) standard deviation score of less than or equal to -3.0

You have normal or elevated growth hormone (serum growth hormone level of at least 10ngm/mL to at least 2 stimuli [insulin, levodopa, arginine, clonidine or glucagon])

Your bone growth plates (epiphyses) are open (as confirmed by radiograph [a type of imaging] of the wrist and hand)

You will NOT use Increlex concurrently (at the same time) with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

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MECASERMIN

RENEWAL CRITERIA

Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:

You will NOT use Increlex concurrently (at the same time) with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

You meet ONE of the following:

- Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
- Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

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Effective: 10/01/25

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MECHLORETHAMINE

Generic	Brand				
MECHLORETHAMINE HCL	VALCHLOR				

GUIDELINES FOR USE

Our guideline named **MECHLORETHAMINE (Valchlor)** requires the following rule(s) be met for approval:

You have Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCL) (a type of blood cancer that affects the skin)

You have received prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids [Targretin (bexarotene), Tazorac (tazarotene)], imiquimod, local radiation therapy)

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MEPOLIZUMAB

Generic	Brand				
MEPOLIZUMAB	NUCALA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
   3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
   4. Hypereosinophilic syndrome (HES: a type of blood disorder)
   5. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)

B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) or allergy medicine
   3. You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
   4. Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   5. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
   4. You have inadequately controlled disease
   5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
   6. Nucala will be used as add-on maintenance treatment (taken on a regular basis)
   7. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus passages with small growths in the nose)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have eosinophilic granulomatosis with polyangiitis, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels)

E. **If you have hypereosinophilic syndrome, approval also requires:**
   1. You are 12 years of age or older
   2. You have had hypereosinophilic syndrome (HES: a type of blood disorder) for at least 6 months without an identifiable non-hematologic (not present in the blood) secondary cause (HES is not caused by another condition)
   3. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   4. You have a blood eosinophil count (a type of lab test) of at least 1000 cells/mcL at the start of therapy
   5. You have a negative FIP1L1-PDFRA test (a type of lab test that detects a type of gene mutation)
   6. You have been stable on hypereosinophilic syndrome (HES: a type of blood disorder) therapy (corticosteroid [such as prednisone]) for at least 4 weeks
   7. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

F. **If you have chronic obstructive pulmonary disease, approval also requires:**
   1. You are 18 years of age or older
   2. You have an eosinophilic phenotype of chronic obstructive pulmonary disease (COPD: a type of inflammatory long-term lung condition)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   4. You have an elevated blood eosinophil count (a type of lab test) of at least 150 cell/mcL at screening (within the past 3 months) OR at least 300 cells/mcL in the previous 12 months
   5. Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
   6. You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype chronic obstructive pulmonary disease (a type of long-term lung condition)

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MEPOLIZUMAB

RENEWAL CRITERIA

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
   3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
   4. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
   5. Hypereosinophilic syndrome (HES: a type of blood disorder)

B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Nucala)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Nucala)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (before starting Nucala) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus passages with small growths in the nose)

D. **If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:**
   1. You have shown a reduction in eosinophilic granulomatosis with polyangiitis (EGPA) symptoms compared to baseline (before starting Nucala), OR you have been able to decrease or eliminate (stop) corticosteroid use
   2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels)

E. **If you have chronic obstructive pulmonary disease, renewal also requires:**
   1. You have an eosinophilic phenotype of chronic obstructive pulmonary disease (COPD: a type of inflammatory long-term lung condition)
   2. Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
   3. You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype chronic obstructive pulmonary disease (a type of long-term lung condition)
   4. You have shown a clinical response as evidenced by ONE of the following:
      a. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Nucala)
      b. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)
      c. You have had an increase in FEV1 (a type of lung test) by at least 5% from pretreatment baseline

(Renewal criteria continued on next page)

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

F. **If you have hypereosinophilic syndrome, renewal also requires:**
   1. You have a reduction in frequency/severity of hypereosinophilic syndrome (HES: a type of blood disorder) flares
   2. You have improved symptoms or reduced oral steroid (such as prednisone) requirements
   3. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

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METFORMIN

Generic	Brand				
METFORMIN HCL	RIOMET, METFORMIN HCL				

GUIDELINES FOR USE

Our guideline named **METFORMIN (Riomet)** requires the following rule(s) be met for approval:

A. You have type 2 diabetes mellitus (a disorder with high blood sugar)
B. You are 10 years of age or older
C. You have a contraindication to (harmful for you to use) or are unable to swallow metformin tablets

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METHOCARBAMOL

Generic	Brand				
METHOCARBAMOL	ATMEKSI				

GUIDELINES FOR USE

Our guideline named **METHOCARBAMOL (Atmeksi)** requires the following rule(s) be met for approval:

A. You have an acute, painful musculoskeletal condition (sudden and severe pain relating to muscles and bones)
B. You have a contraindication to (harmful for you to use) or are unable to swallow generic methocarbamol tablets

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METHOTREXATE - JYLAMVO

Generic	Brand				
METHOTREXATE	JYLAMVO				

GUIDELINES FOR USE

Our guideline named **METHOTREXATE - JYLAMVO** requires the following rule(s) be met for approval:

You have ONE of the following:
- Acute lymphoblastic leukemia (ALL: a type of blood cancer)
- Mycosis fungoides (cutaneous T-cell lymphoma) (a type of blood cancer affecting the skin)
- Relapsed or refractory non-Hodgkin lymphoma (a type of blood cancer that has returned or did not respond to treatment)
- Rheumatoid arthritis (a type of joint condition)
- Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Severe psoriasis (a type of skin condition)

If you have acute lymphoblastic leukemia, approval also requires:
- Jylamvo will be used as part of a combination chemotherapy maintenance regimen (a type of therapy to treat cancer)
- You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

If you have mycosis fungoides (cutaneous T-cell lymphoma), approval also requires:
- You are 18 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

If you have relapsed or refractory non-Hodgkin lymphoma, approval also requires:
- You are 18 years of age or older
- Jylamvo will be used as part of a metronomic combination chemotherapy regimen (a type of therapy to treat cancer where lower doses are given over a long period to reduce side effects)
- You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

If you have rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

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METHOTREXATE - JYLAMVO

GUIDELINES FOR USE (CONTINUED)

If you have severe psoriasis, approval also requires:

You are 18 years of age or older

You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

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Effective: 01/01/26

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METHOTREXATE - XATMEP

Generic	Brand				
METHOTREXATE	XATMEP				

GUIDELINES FOR USE

Our guideline named **METHOTREXATE - XATMEP** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acute lymphoblastic leukemia (ALL: a type of blood cancer)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. **If you have acute lymphoblastic leukemia, approval also requires:**
   1. Xatmep will be used as part of a combination chemotherapy maintenance regimen (a type of therapy to treat cancer)
   2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

C. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You had an insufficient response to (medication did not work) or are intolerant of (side effects) first-line therapy, including non-steroidal anti-inflammatory drugs (NSAIDs such as ibuprofen)
   2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

Effective: 07/01/26

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METHOXY PEG-EPOETIN BETA

Generic	Brand				
METHOXY PEG-EPOETIN BETA	MIRCERA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for approval:

You have anemia (a type of blood condition) associated with chronic (long-term) kidney disease (CKD)

You are 3 months of age or older

You will NOT use Micera concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Epogen [epoetin alfa], Procrit [epoetin alfa]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you are 18 years of age or older, approval also requires:

You have tried the preferred medication: Retacrit (epoetin alfa-epbx)

Your hemoglobin level (type of blood test) is less than 10g/dL

If you are between 3 months and 17 years of age, approval also requires:

You are changing from another erythropoiesis-stimulating agent (ESA, such as Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after your hemoglobin level (type of blood test) has been stabilized with that ESA

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METHOXY PEG-EPOETIN BETA

RENEWAL CRITERIA

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for renewal:

You have anemia (a type of blood condition) associated with chronic (long-term) kidney disease (CKD)

You are 3 months of age or older

You will NOT use Micera concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Epogen [epoetin alfa], Procrit [epoetin alfa]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

If you are 18 years of age or older, renewal also requires ONE of the following:

- Your hemoglobin level (type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level (type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
- Your hemoglobin level (type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
- Your hemoglobin level (type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

If you are between 3 months and 17 years of age, renewal also requires ONE of the following:

- Your hemoglobin level (type of blood test) is less than 12g/dL
- Your hemoglobin level (type of blood test) has reached 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

Effective: 10/01/25

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METHYLNALTREXONE

Generic	Brand			
METHYLNALTREXONE BROMIDE	RELISTOR			

GUIDELINES FOR USE

Our guideline named **METHYLNALTREXONE (Relistor)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Opioid-induced constipation (a type of bowel disorder caused by drugs used to treat pain) with chronic (long-term) non-cancer pain
   2. Opioid-induced constipation with advanced illness or pain caused by active cancer

B. **If you have opioid-induced constipation with chronic non-cancer pain, approval also requires:**
   1. You are 18 years of age or older
   2. You have chronic non-cancer pain, including chronic pain related to prior cancer or its treatment
   3. You do NOT require frequent opioid dosage escalation (increase)
   4. You have been taking opioids for at least four weeks
   5. You have tried or have a contraindication to (harmful for you to use) the preferred medications: Symproic (naldemedine) AND Movantik (naloxegol)

C. **If you have opioid-induced constipation with advanced illness or pain caused by active cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your request is for Relistor injection
   3. You require opioid dosage escalation (increase) for palliative care (treatment for comfort from symptoms)

Effective: 01/01/25

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METHYLTESTOSTERONE

Generic	Brand				
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST, METHYLTESTOS-TERONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Delayed puberty not due to a pathological disorder (not due to a disease) in a male
- Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following showing you have low testosterone levels:
  - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
  - You have a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
- You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

(Initial criteria continues on next page)

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate

If you are a female with metastatic breast cancer, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate
- You meet ONE of the following:
  - You are postmenopausal (after menopause)
  - You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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METHYLTESTOSTERONE

RENEWAL CRITERIA

Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Delayed puberty not due to a pathological disorder (not due to a disease) in a male
- Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
- You have NOT received more than two 6-month courses of testosterone replacement therapy

If you are a female with metastatic breast cancer, renewal also requires ONE of the following:
- You are postmenopausal (after menopause)
- You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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METOCLOPRAMIDE

Generic	Brand				
METOCLOPRAMIDE HCL	GIMOTI				

GUIDELINES FOR USE

Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:

You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (a disorder from high blood sugar that causes delayed emptying of food from the stomach)

You are 18 years of age or older

You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: metoclopramide ODT (orally disintegrating tablet)

Effective: 03/25/26

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METOPROLOL

Generic	Brand				
METOPROLOL TARTRATE	LOPRESSOR				

GUIDELINES FOR USE

Our guideline named **METOPROLOL (Lopressor)** requires the following rule(s) be met for approval:

You have a contraindication to (harmful for you to use) or are unable to swallow metoprolol tartrate tablets

Effective: 08/04/25

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METRELEPTIN

Generic	Brand				
METRELEPTIN	MYALEPT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **METRELEPTIN (Myalept)** requires the following rule(s) be met for approval:

You have congenital or acquired generalized lipodystrophy (abnormal distribution of fat in the body)

Myalept will be used as an adjunct (add-on) to diet as replacement therapy to treat the complications of leptin deficiency (low level of a type of hormone)

Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

You have diabetes mellitus (a disorder with high blood sugar), insulin resistance (a condition where cells in the body do not respond to a type of hormone), OR a fasting hypertriglyceridemia (high levels of fat in the blood) of greater than 200mg/dL

RENEWAL CRITERIA

Our guideline named **METRELEPTIN (Myalept)** requires the following rule(s) be met for renewal:

You have congenital or acquired generalized lipodystrophy (abnormal distribution of fat in the body)

You have shown clinical benefit (improvement) with the use of Myalept (such as a reduction in glucose levels [lower level of blood sugar], reduction of insulin resistance [cells in the body are more responsive to a type of hormone], or reduction of triglycerides [lower level of fat in the blood])

Effective: 01/01/26

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METRONIDAZOLE

Generic	Brand				
METRONIDAZOLE	LIKMEZ				

GUIDELINES FOR USE

Our guideline named **METRONIDAZOLE (Likmez)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Trichomoniasis (a type of infection caused by a parasite)
- Acute intestinal amebiasis (amoebic dysentery: a type of infection of the intestines) OR amebic liver abscess (a collection of pus in the liver caused by a parasite)
- Serious infections caused by susceptible anaerobic bacteria, such as *Bacteroides* species, *Clostridium* species, *Peptococcus* species (infections caused by types of bacteria that can be treated with metronidazole)

You have a contraindication to (harmful for you to use) or are unable to swallow metronidazole tablets

For the treatment of trichomoniasis or serious infections caused by susceptible anaerobic bacteria, approval also requires:

You are 18 years of age or older

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METYROSINE

Generic	Brand				
METYROSINE	DEMSER, METYROSINE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **METYROSINE (Demser)** requires the following rule(s) be met for approval:
You have pheochromocytoma (a type of rare tumor)
You will be using the requested medication for ONE of the following:
- Preoperative preparation for surgery
- Management of malignant (cancerous) pheochromocytoma when surgery is contraindicated (harmful for you to have)
- Chronic (long term) treatment of malignant pheochromocytoma

You have a non-metastatic pheochromocytoma (tumor has not spread to other parts of the body)
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist-oncologist (a type of cancer doctor)
If you are awaiting surgery, approval also requires:
- The requested medication will be in combination with an alpha-adrenergic receptor blocker (such as doxazosin, terazosin, prazosin, phenoxybenzamine)

RENEWAL CRITERIA

NOTE: For the request of pre-operative preparation for surgery, please refer to the Initial Criteria section.

Our guideline named **METYROSINE (Demser)** requires the following rule(s) be met for renewal:
You have pheochromocytoma (a type of rare tumor)
You will be using the requested medication for ONE of the following:
- Management of malignant (cancerous) pheochromocytoma when surgery is contraindicated (harmful for you to have)
- Chronic (long term) treatment of malignant pheochromocytoma

You are stable or have shown clinical improvement while on therapy (treatment)

Effective: 05/12/25

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MIDAZOLAM

Generic	Brand				
MIDAZOLAM	NAYZILAM				

GUIDELINES FOR USE

Our guideline named **MIDAZOLAM (Nayzilam)** requires the following rule(s) be met for approval:

A. You have epilepsy (a type of brain disorder)
B. You are 12 years of age or older
C. Nayzilam will be used for the acute (short-term) treatment of intermittent, stereotypic episodes of frequent seizure activity (a condition of increased seizure activity) (seizure clusters, acute repetitive seizures) that are different from your usual seizure pattern

Effective: 07/01/26

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MIDOSTAURIN

Generic	Brand				
MIDOSTAURIN	RYDAPT				

GUIDELINES FOR USE

Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
- Aggressive systemic mastocytosis (ASM: a type of blood disorder)
- Systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood cancer)
- Mast cell leukemia (MCL: a type of blood cancer)

If you have acute myeloid leukemia, approval also requires:
- You are 18 years of age or older
- You are newly diagnosed (such as you are starting or previously started Rydapt treatment at the time your condition was identified)
- Your cancer is FLT3 mutation-positive (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
- Rydapt will be used in combination with standard cytarabine and daunorubicin induction (initial treatment) OR with cytarabine consolidation chemotherapy (treatment following initial therapy)

If you have aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, or mast cell leukemia, approval also requires:
- You are 18 years of age or older

Effective: 08/11/25

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MIFEPRISTONE

Generic	Brand				
MIFEPRISTONE	KORLYM, MIFEPRISTONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:
You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
You are 18 years of age or older
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
Your hypercortisolism (high levels of cortisol) is NOT due to chronic glucocorticoids (long-term use of a class of medications that consists of steroids, such as prednisone)
You also have type 2 diabetes mellitus (a disorder with high blood sugar) OR glucose intolerance (a condition that results in high blood sugar)
You have failed surgical treatment (surgery did not work) for Cushing's syndrome (a type of hormone disorder) OR you are NOT a candidate for surgery
You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ketoconazole
You will NOT use the requested medication concurrently (at the same time) with other medications to lower cortisol (such as Recorlev [levoketoconazole], Isturisa [osilodrostat]) for the treatment of Cushing’s disease/syndrome (a type of hormone disorder)
Your diagnosis is confirmed by ONE of the following:
- A 24-hour urine free cortisol (a type of test that measures the amount of cortisol in the urine) (at least 2 tests to confirm)
- An overnight 1mg dexamethasone test (a type of diagnostic test)
- A late-night salivary cortisol (a type of test that measures the amount of cortisol in the saliva at night) (at least 2 tests to confirm)

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MIFEPRISTONE

RENEWAL CRITERIA

Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:

You have endogenous Cushing's syndrome (CS: a type of hormone disorder)

You continue to have improvement of glucose tolerance or stable glucose tolerance (such as reduced hemoglobin A1C level [a type of lab test], improved fasting glucose)

You continue to tolerate Korlym (mifepristone)

You are NOT a candidate for surgery OR you have failed surgery (surgery did not work) for Cushing's syndrome (a type of hormone disorder)

You will NOT use the requested medication concurrently (at the same time) with other medications to lower cortisol (such as Recorlev [levoketoconazole], Isturisa [osilodrostat]) for the treatment of Cushing’s disease/syndrome (a type of hormone disorder)

Effective: 04/01/26

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MIGALASTAT

Generic	Brand			
MIGALASTAT	GALAFOLD			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:

A. You have Fabry disease (a rare genetic disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor), cardiologist (a type of heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
D. You have an amenable (responsive) galactosidase alpha (GLA) gene variant (abnormal change in a type of gene) based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by a clinical genetics professional as the cause of disease (pathogenic or likely pathogenic)
E. You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
F. You are symptomatic OR have evidence of injury from GL-3 (globotriaosylceramide: a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury may include decreased GFR (glomerular filtration rate: a tool for evaluating kidney function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (magnetic resonance imaging: type of imaging lab), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
G. **If you are a female, approval also requires:**
    1. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing
H. **If you are a male, approval also requires ONE of the following:**
    1. You do NOT have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
    2. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing

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MIGALASTAT

RENEWAL CRITERIA

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:

A. You have Fabry disease (a rare genetic disease)
B. You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
C. You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
    1. Symptoms (such as pain, hypohidrosis [less sweating]/anhidrosis [no sweating], exercise intolerance, gastrointestinal [GI] symptoms, angiokeratomas [dark red-blue raised spots on the skin], abnormal cornea [a part of the eye], tinnitus [ringing in the ears]/hearing loss)
    2. Imaging (such as brain/cardiac MRI [magnetic resonance imaging: type of imaging lab], DEXA [a type of bone scan], renal [kidney] ultrasound)
    3. Laboratory or histological (viewed by microscope) testing (such as GL-3 [globotriaosylceramide: a type of fat] in plasma/urine, renal biopsy [removal of cells or tissue from the body for examination])

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MIGLUSTAT-OPFOLDA

Generic	Brand				
MIGLUSTAT	OPFOLDA				

GUIDELINES FOR USE

Our guideline named **MIGLUSTAT-OPFOLDA** requires the following rule(s) be met for approval:

A. You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)
B. You are 18 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. You are NOT improving on your current enzyme replacement therapy (ERT) (such as Lumizyme [alglucosidase alfa])
E. Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

Effective: 01/01/25

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MIGLUSTAT-ZAVESCA

Generic	Brand				
MIGLUSTAT	ZAVESCA, YARGESA, MIGLUSTAT				

GUIDELINES FOR USE

Our guideline named **MIGLUSTAT-ZAVESCA (Yargesa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Mild to moderate type 1 Gaucher disease (a type of genetic condition)
   2. Niemann-Pick disease type C (NPC: a type of genetic condition)

B. **If you have mild to moderate type 1 Gaucher disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as monotherapy (one drug treatment)
   3. Enzyme replacement therapy (a type of treatment) is not a therapeutic option for you (due to reasons such as allergy, hypersensitivity [allergic reaction], poor access to veins)

C. **If you have Niemann-Pick disease type C, approval also requires:**
   1. The requested medication will be used in combination with Miplyffa (arimoclomol)

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MILTEFOSINE

Generic	Brand				
MILTEFOSINE	IMPAVIDO				

GUIDELINES FOR USE

Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Visceral leishmaniasis caused by *Leishmania donovani* (a type of parasitic disease that affects the organs)
- Cutaneous leishmaniasis caused by *Leishmania braziliensis, Leishmania guyanensis, or Leishmania panamensis* (a type of parasitic disease that affects the skin)
- Mucosal leishmaniasis caused by *Leishmania braziliensis* (a type of parasitic disease that affects the inside of the mouth, throat, and nose)

The *Leishmaniasis* species have been identified by ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
- Stained slides (using tissue from biopsy specimens [removal of tissue from the body for examination], impression smears [removal of cells from the body for examination] or dermal scrapings [removal of cells from the body for examination])
- Culture medium (a type of lab test)
- Polymerase chain reaction (PCR: a type of lab test)
- Serologic testing (a type of blood test, such as rK39 Rapid Test)

Effective: 02/01/26

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MINOCYCLINE

Generic	Brand				
MINOCYCLINE HCL	EMROSI				

GUIDELINES FOR USE

Our guideline named **MINOCYCLINE (Emrosi)** requires the following rule(s) be met for approval:

A. You have rosacea (a type of skin condition)
B. You are 18 years of age or older
C. You have inflammatory lesions (papules and pustules: small bumps on the skin) associated with rosacea
D. You have tried or have a contraindication to (harmful for you to use) ONE generic oral minocycline or doxycycline

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MINOCYCLINE MICROSPHERES

Generic	Brand			
MINOCYCLINE HCL MICROSPHERES	ARESTIN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an oral health care professional
D. You do NOT have a history of minocycline or tetracycline sensitivity or allergy
E. You do NOT have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. Arestin will be administered by an oral health care professional
G. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
H. Arestin will NOT be used for an acutely abscessed periodontal pocket (infection with pus-filled pocket)
I. Arestin will NOT be used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus (a disorder with high blood sugar)
    2. Chemotherapy (a type of drug used to treat cancer)
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. Arestin will NOT be used in the regeneration (reconstruction) of alveolar bone (part of the bone that has tooth sockets), either in preparation for or in conjunction (together) with the placement of endosseous (dental) implants or in the treatment of failing implants

RENEWAL CRITERIA

Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:

A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
B. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

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MIRDAMETINIB

Generic	Brand				
MIRDAMETINIB	GOMEKLI				

GUIDELINES FOR USE

Our guideline named **MIRDAMETINIB (Gomekli)** requires the following rule(s) be met for approval:

A. You have neurofibromatosis type 1 (NF1: a type of skin and nervous system disorder)
B. You are 2 years of age or older
C. You have symptomatic plexiform neurofibromas (PN: tumors that grow along the nerves) that cannot be completely resected (cannot be completely removed by surgery)

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MIRIKIZUMAB-MRKZ

Generic	Brand				
MIRIKIZUMAB-MRKZ	OMVOH				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for approval:
You have ONE of the following:

1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe ulcerative colitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

If you have moderate to severe Crohn's disease, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

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MIRIKIZUMAB-MRKZ

RENEWAL CRITERIA

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

C. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

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MIRVETUXIMAB SORAVTANSINE-GYNX (NSA)

Generic	Brand				
MIRVETUXIMAB SORAVTANSINE-GYNX	ELAHERE				

GUIDELINES FOR USE

Our guideline named **MIRVETUXIMAB SORAVTANSINE-GYNX (Elahere)** requires the following rule(s) be met for approval:

A. You have platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that do not respond to a type of cancer treatment)
B. You are 18 years of age or older
C. Your tumor is folate receptor-alpha (FRa: a type of protein) positive as determined by a Food and Drug Administration (FDA)-approved test
D. You have received one to three prior systemic treatment regimen(s) (such as bevacizumab, Lynparza)
E. You will complete an ophthalmic (eye) exam, including visual acuity (sharpness of vision) and slit lamp exam (a type of eye exam), before starting Elahere and at the recommended scheduled times

Effective: 04/01/23

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MITAPIVAT-AQVESME

Generic	Brand				
MITAPIVAT SULFATE	AQVESME				

GUIDELINES FOR USE

Our guideline named **MITAPIVAT-AQVESME** requires the following rule(s) be met for approval:
You have alpha-thalassemia or beta-thalassemia (types of blood condition)
You are 18 years of age or older
Aqvesme will be used for the treatment of anemia (a type of blood condition)

Effective: 01/19/26

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MITAPIVAT-PYRUKYND

Generic	Brand				
MITAPIVAT SULFATE	PYRUKYND				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MITAPIVAT-PYRUKYND** requires the following rule(s) be met for approval:

A. You have hemolytic anemia (a type of blood condition) due to pyruvate kinase (PK: a type of enzyme) deficiency
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. You have a documented presence of at least 2 mutant alleles in the PKLR gene (two copies of a gene with abnormal changes), of which at least 1 is a missense mutation (abnormal changes in a type of gene)
E. You have a documented hemoglobin (a type of protein in red blood cells) concentration of less than or equal to 10 g/dL

RENEWAL CRITERIA

Our guideline named **MITAPIVAT-PYRUKYND** requires the following rule(s) be met for renewal:

A. You have hemolytic anemia (a type of blood condition) due to pyruvate kinase (PK: a type of enzyme) deficiency
B. You have had clinical benefit while on Pyrukynd

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MITOMYCIN

Generic	Brand				
MITOMYCIN	JELMYTO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for approval:
You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
You are 18 years of age or older
Therapy is prescribed by or in consultation with an oncologist (doctor who specializes in cancer) or urologist (doctor who specializes in the urinary tract and male reproductive organs)

RENEWAL CRITERIA

Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for renewal:
You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
You were reassessed at no sooner than 3 months after initiation of Jelmyto
You showed complete response at the time of assessment

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MITOXANTRONE (NSA)

Generic	Brand			
MITOXANTRONE HCL	NOVANTRONE			

GUIDELINES FOR USE

Our guideline named **MITOXANTRONE** requires ONE of following rules be met for approval:
The medication is prescribed by or given in consultation with an oncologist (tumor/cancer doctor)
You have ONE of the following:
Pain related to advanced refractory prostate cancer
Acute nonlymphocytic leukemia (type of white blood cell cancer)
Secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis (disease where immune system attacks nerves)

Effective: 07/01/20

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MOGAMULIZUMAB-KPKC (NSA)

Generic	Brand			
MOGAMULIZUMAB-KPKC	POTELIGEO			

GUIDELINES FOR USE

Our guideline named **MOGAMULIZUMAB-KPKC (Poteligeo)** requires the following rule(s) be met for approval:
You have Mycosis Fungoides or Sezary syndrome (types of blood cancers that affect the skin)
You are 18 years of age or older
You have relapsed or refractory disease (disease has returned or not responsive to therapy)
You have tried and failed at least one prior systemic therapy (treatment that travels in the blood throughout the body)

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MOMELOTINIB

Generic	Brand				
MOMELOTINIB DIHYDROCHLORIDE	OJJAARA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MOMELOTINIB (Ojjaara)** requires the following rule(s) be met for approval:

A. You have intermediate or high-risk myelofibrosis (MF: a type of blood cancer), such as primary MF (MF that developed on its own) or secondary MF (MF that developed from another blood disorder, such as post-polycythemia vera [PV: a type of blood cancer] or post-essential thrombocythemia [ET: a type of blood disease])
B. You are 18 years of age or older
C. You have anemia (a type of blood condition)

RENEWAL CRITERIA

Our guideline named **MOMELOTINIB (Ojjaara)** requires the following rule(s) be met for renewal:

A. You have intermediate or high-risk myelofibrosis (MF: a type of blood cancer), such as primary MF (MF that developed on its own) or secondary MF (MF that developed from another blood disorder, such as post-polycythemia vera [PV: a type of blood cancer] or post-essential thrombocythemia [ET: a type of blood disease])
B. You have shown symptom improvement by meeting ONE of the following:
    1. You have had at least a 50 percent reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v4.0)
    2. You have had at least a 50 percent reduction in palpable (can be felt by external examination) spleen length
    3. You have had a spleen volume reduction of at least 35 percent from baseline (before treatment)
    4. You have improvement in anemia (a type of blood condition) (such as increased hemoglobin [a type of protein in red blood cells], reduced transfusion [adding blood to your body] requirements)

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MONOMETHYL FUMARATE

Generic	Brand				
MONOMETHYL FUMARATE	BAFIERTAM				

GUIDELINES FOR USE

Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

You are 18 years of age or older

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

Effective: 01/01/26

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MOSUNETUZUMAB-AXGB (NSA)

Generic	Brand				
MOSUNETUZUMAB-AXGB	LUNSUMIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MOSUNETUZUMAB-AXGB (Lunsumio)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or did not respond to treatment)
B. You are 18 years of age or older
C. You have tried two or more lines of systemic therapy (treatment that targets the entire body)

RENEWAL CRITERIA

Our guideline named **MOSUNETUZUMAB-AXGB (Lunsumio)** requires the following rule(s) be met for renewal:

A. You have relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or does not respond to treatment)
B. You have achieved a partial response to treatment
C. You have not previously received more than 17 cycles of treatment

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MOTIXAFORTIDE (NSA)

Generic	Brand				
MOTIXAFORTIDE ACETATE	APHEXDA				

GUIDELINES FOR USE

Our guideline named **MOTIXAFORTIDE (Aphexda)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (MM: a type of blood cancer)
B. Aphexda will be used in combination with filgrastim or its biosimilars (such as Neupogen, Nivestym)
C. Aphexda will be used to mobilize hematopoietic stem cells to the peripheral blood for collection (a type of blood cell is stimulated to be collected from your blood) followed by autologous stem cell transplantation (a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

Effective: 12/01/23

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MOXETUMOMAB PASUDOTOX (NSA)

Generic	Brand			
MOXETUMOMAB PASUDOTOX-TDFK	LUMOXITI			

GUIDELINES FOR USE

Our guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires the following rule(s) be met for approval:
You have hairy cell leukemia (HCL: type of blood and bone marrow cancer)
You are 18 years of age or older
You have relapsed or refractory disease (disease has returned or is not responsive to therapy)
You have received at least two prior systemic therapies, including treatment with a purine nucleoside analog (type of drug that treats certain blood cancers)
You have NOT previously received 6 cycles of Lumoxiti

Effective: 04/10/21

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MYCOPHENOLATE

Generic	Brand				
MYCOPHENOLATE MOFETIL	MYHIBBIN				

GUIDELINES FOR USE

Our guideline named **MYCOPHENOLATE (Myhibbin)** requires the following rule(s) be met for approval:

A. The request is for the prophylaxis (prevention) of an organ rejection
B. You have a history of an allogeneic (from a donor) kidney, heart or liver transplant
C. Myhibbin will be used in combination with other immunosuppressants (such as cyclosporine)
D. You have tried or have a contraindication to (harmful for you to use) generic mycophenolate mofetil tablets
E. You are unable to swallow mycophenolate mofetil tablets

Effective: 07/01/24

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NAFARELIN

Generic	Brand				
NAFARELIN ACETATE	SYNAREL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for approval:
You have ONE of the following:
Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
Moderate to severe pain from endometriosis (condition affecting the uterus)
Central precocious puberty (CPP: early sexual development in girls and boys)
If you have moderate to severe pain from endometriosis, approval also requires:
You are 18 years of age or older
Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medications: a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
You are NOT using Synarel concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone acetate], Lupron Depot [leuprolide])
You have NOT received more than 6 months of treatment with Synarel per lifetime
If you are female and have central precocious puberty, approval also requires:
You are 2 years of age or older
Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
You are/were younger than 8 years of age when your condition started
You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)
(Initial criteria continued on next page)

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

If you are male and have central precocious puberty, approval also requires:
You are 2 years of age or older
Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
You are/were younger than 9 years of age when your condition started
You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or pain from endometriosis, please refer to the Initial Criteria section.

Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for renewal:
You have central precocious puberty (CPP: early sexual development in girls and boys)
Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
You have NOT reached the actual age which corresponds to your current pubertal age

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Effective: 08/07/26

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NALTREXONE - BUPROPION

Generic	Brand				
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for approval:
The request is for weight loss or weight management
You are 18 years of age or older
You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
You meet ONE of the following before starting weight loss therapy:
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
- You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
- You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

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NALTREXONE - BUPROPION

RENEWAL CRITERIA

Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for renewal:
The request is for weight loss or weight management
You meet ONE of the following before starting weight loss therapy:
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
- You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
- You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

You have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets two times a day)

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NATALIZUMAB

Generic	Brand				
NATALIZUMAB	TYSABRI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

(Initial criteria continued on next page)

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NATALIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older
   2. Tysabri will be used as monotherapy (one drug treatment)
   3. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

(Renewal criteria continued on next page)

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NATALIZUMAB

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
   3. If you have received at least 12 months of Tysabri therapy, renewal also requires:
      a. You have NOT received more than 3 months of corticosteroids within the past 12 months to control your Crohn's disease while on Tysabri
   4. If you have only received 6 months of Tysabri therapy, renewal also requires:
      a. You are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tysabri therapy)

C. **If you have a relapsing form of multiple sclerosis, renewal also requires:**
   1. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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NATALIZUMAB-SZTN

Generic	Brand				
NATALIZUMAB-SZTN	TYRUKO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NATALIZUMAB-SZTN (Tyruko)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn’s disease (a type of bowel disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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NATALIZUMAB-SZTN

INITIAL CRITERIA (CONTINUED)

C. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older
   2. Tyruko will be used as monotherapy (one drug treatment)
   3. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named **NATALIZUMAB-SZTN (Tyruko)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Skyrizi (risankizumab-rzaa)
   c. Tremfya (guselkumab)
   d. Omvoh (mirikizumab-mrkz)
   e. Adalimumab-ryvk/adalimumab-aaty
   f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
3. If you have received at least 12 months of Tyruko therapy, renewal also requires:
   a. You have NOT received more than 3 months of corticosteroids within the past 12 months to control your Crohn's disease while on Tyruko
4. If you have only received 6 months of Tyruko therapy, renewal also requires:
   a. You are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tyruko therapy)

C. **If you have a relapsing form of multiple sclerosis, renewal also requires:**
   1. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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NAVEPEGRITIDE

Generic	Brand				
NAVEPEGRITIDE	YUVIWEL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NAVEPEGRITIDE (Yuviwel)** requires the following rule(s) be met for approval:
You have achondroplasia (a type of bone condition)
You have open epiphyses (the end part of a long bone)
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), orthopedist (a type of doctor who specializes in bones, joints, muscles, ligaments, tendons and nerves), or medical geneticist (doctor who treats gene disorders)
You will NOT use Yuviwel concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Voxzogo [vosoritide]) for the treatment of achondroplasia (a type of bone condition)

RENEWAL CRITERIA

Our guideline named **NAVEPEGRITIDE (Yuviwel)** requires the following rule(s) be met for renewal:
You have achondroplasia (a type of bone condition)
You have experienced an improvement in annual growth velocity (rate of growth) since baseline (before treatment with Yuviwel)
Your epiphyses (the end part of a long bone) remain open
You will NOT use Yuviwel concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Voxzogo [vosoritide]) for the treatment of achondroplasia (a type of bone condition)

Effective: 03/14/26

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NAXITAMAB-GQGK

Generic	Brand				
NAXITAMAB-GQGK	DANYELZA				

GUIDELINES FOR USE

Our guideline named **NAXITAMAB-GQGK (Danyelza)** requires the following rule(s) be met for approval:

You have relapsed or refractory high-risk neuroblastoma in the bone or bone marrow (a type of cancer that has returned or no longer responds to treatment)

You are 1 year of age or older

Danyelza will be used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) (a type of medication used to make more white blood cells)

You have shown a partial response (the cancer partly responded to treatment, but still did not go away), minor response, or stable disease to prior therapy

Effective: 01/01/26

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NECITUMUMAB (NSA)

Generic	Brand			
NECITUMUMAB	PORTRAZZA			

GUIDELINES FOR USE

Our guideline named **NECITUMUMAB (Portrazza)** requires the following rule(s) be met for approval:

The medication will be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC; type of lung cancer that has spread to other parts of the body) in combination with gemcitabine and cisplatin

Effective: 04/10/21

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NEDOSIRAN

Generic	Brand				
NEDOSIRAN SODIUM	RIVFLOZA				

GUIDELINES FOR USE

Our guideline named **NEDOSIRAN (Rivfloza)** requires the following rule(s) be met for approval:
You have primary hyperoxaluria type 1 (PH1: a type of rare genetic disorder)
You are 2 years of age or older
You have relatively preserved kidney function (such as an estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] is at least 30mL/min/1.73m[2])

Effective: 02/01/26

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NEMOLIZUMAB-ILTO

Generic	Brand				
NEMOLIZUMAB-ILTO	NEMLUVIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   2. Prurigo nodularis (PN: a type of skin condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)

B. **If you have prurigo nodularis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
   3. You have multiple pruriginous lesions (wounds)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine
   5. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis (a type of skin condition)

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NEMOLIZUMAB-ILTO

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. You will use Nemluvio in combination with a topical corticosteroid (such as triamcinolone, clobetasol) and/or calcineurin inhibitor (such as tacrolimus, pimecrolimus)
   3. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   4. Your disease is not adequately controlled with clinical standard of care topical prescription therapies (such as topical corticosteroids [such as hydrocortisone, clobetasol propionate, halobetasol propionate], topical PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Adquey (difamilast), Zoryve (roflumilast)], topical aryl hydrocarbon receptor (AhR) agonist [such as Vtama (tapinarof)], topical JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], topical calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)]), with or without prior phototherapy (light therapy)
   5. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
   6. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm]) and are switching to Nemluvio
      b. You have atopic dermatitis (a type of skin condition) covering at least 10% of body surface area (BSA)
      c. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)

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NEMOLIZUMAB-ILTO

RENEWAL CRITERIA

Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Prurigo nodularis (PN: a type of skin condition)
   2. Moderate to severe atopic dermatitis (AD: a type of skin condition)

B. **If you have prurigo nodularis, renewal also requires:**
   1. You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
   2. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis (a type of skin condition)

C. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have shown improvement while on Nemluvio
   2. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

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NERANDOMILAST

Generic	Brand				
NERANDOMILAST	JASCAYD				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NERANDOMILAST (Jascayd)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
- Progressive pulmonary fibrosis (PPF: a type of lung condition with gradual scarring of the lungs)

If you have idiopathic pulmonary fibrosis, approval also requires:

- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
- You have a usual interstitial pneumonia (UIP) pattern (a specific type of lung scarring) as shown by high-resolution computed tomography (HRCT: type of imaging test) alone or by a combination of surgical lung biopsy (removal of cells or tissue from the lung for examination) and HRCT
- You do NOT have other known causes of interstitial lung disease (ILD: a type of lung condition) (such as connective tissue disease [a type of autoimmune disorder], drug toxicity, asbestos [a type of mineral that can be toxic] or beryllium [a type of metal that can be toxic] exposure, hypersensitivity pneumonitis [a type of lung condition], systemic sclerosis [a type of autoimmune disorder], rheumatoid arthritis [a type of joint condition], radiation, sarcoidosis [a type of inflammatory disorder], bronchiolitis obliterans organizing pneumonia [a type of lung condition], human immunodeficiency virus infection [HIV: an immune system disease caused by a virus], viral hepatitis [a type of liver inflammation], cancer)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ofev (nintedanib), pirfenidone (Esbriet)

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NERANDOMILAST

INITIAL CRITERIA (CONTINUED)

If you have progressive pulmonary fibrosis, approval also requires:

- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
- You have interstitial lung disease with a progressive phenotype (trait) (PF-ILD)
- Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities [additional health conditions] such as infection, heart failure)
- You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing) (such as reticular abnormality [a specific pattern on imaging studies] with traction bronchiectasis [a condition where the lungs' airway becomes damaged, widened, and thickened] with or without honeycombing)
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ofev (nintedanib)

RENEWAL CRITERIA

Our guideline named **NERANDOMILAST (Jascayd)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
- Progressive pulmonary fibrosis (PPF: a type of lung condition with gradual scarring of the lungs)

You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

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NERATINIB

Generic	Brand				
NERATINIB MALEATE	NERLYNX				

GUIDELINES FOR USE

Our guideline named **NERATINIB (Nerlynx)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Early stage (stage I-III) breast cancer
- Advanced or metastatic breast cancer (cancer that has spread to nearby tissue or has spread to other parts of the body)

If you have early stage (stage I-III) breast cancer, approval also requires:
- You are 18 years of age or older
- Your tumor is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- Nerlynx will be used as extended adjuvant (additional) therapy following trastuzumab based therapy
- Nerlynx is being requested within 2 years of completing the last trastuzumab dose

If you have advanced or metastatic breast cancer, approval also requires:
- You are 18 years of age or older
- Your tumor is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- Nerlynx will be used in combination with capecitabine
- You have received two or more prior anti-HER2 based regimens in the metastatic setting

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NILOTINIB

Generic	Brand				
NILOTINIB HCL	TASIGNA, NILOTINIB HCL				
NILOTINIB TARTRATE	DANZITEN				

GUIDELINES FOR USE

Our guideline named **NILOTINIB (Tasigna, Danziten)** requires the following rule(s) be met for approval:

You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)

If your cancer is newly diagnosed (such as you are starting or previously started nilotinib treatment at the time your condition was identified), approval also requires:

You are 1 year of age or older

Your cancer is in chronic phase

If your cancer has been previously treated, approval also requires:

Your cancer is in chronic phase or accelerated phase

You meet ONE of the following:

- You are 1 to 17 years of age AND you are resistant (not responding to treatment) or intolerant (side effect) to prior treatment with other tyrosine kinase inhibitors (TKIs, such as Gleevec [imatinib], Sprycel [dasatinib], Bosulif [bosutinib])
- You are 18 years of age or older AND you are resistant or intolerant to prior treatment that included Gleevec (imatinib)

You had a mutational analysis (a type of lab test) prior to the start of treatment AND the requested medication is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

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NIMODIPINE SOLUTION

Generic	Brand				
NIMODIPINE	NYMALIZE, NIMODIPINE				

GUIDELINES FOR USE

Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:

A. You have a history of a subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain)
B. You are 18 years of age or older
C. Your subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) is from a ruptured intracranial berry aneurysm (part of blood vessel in your brain has expanded and burst) within the past 21 days
D. You have a contraindication to (harmful for you to use) or are unable to swallow generic nimodipine capsules

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NINTEDANIB

Generic	Brand				
NINTEDANIB ESYLATE	OFEV				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
- Chronic fibrosing interstitial lung disease with a progressive phenotype (PF-ILD: a type of lung condition with scarring of the lungs caused by different underlying diseases/conditions that worsen over time)

If you have idiopathic pulmonary fibrosis, approval also requires:
- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
- You have a usual interstitial pneumonia pattern (UIP: a specific type of lung scarring) as shown by high-resolution computed tomography (HRCT: type of imaging test) alone or by a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
- You do NOT have other known causes of interstitial lung disease (ILD: a type of lung condition) (such as connective tissue disease [a type of autoimmune disorder], drug toxicity, asbestos [a type of mineral that can be toxic] or beryllium [a type of metal that can be toxic] exposure, hypersensitivity pneumonitis [type of lung condition], systemic sclerosis [a type of autoimmune disorder], rheumatoid arthritis [a type of joint condition], radiation, sarcoidosis [a type of inflammatory disorder], bronchiolitis obliterans organizing pneumonia [a type of lung condition], human immunodeficiency virus [HIV: an immune system disease caused by a virus] infection, viral hepatitis [a type of liver inflammation], cancer)
- You will NOT use Ofev concurrently (at the same time) with Esbriet

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

If you have systemic sclerosis-associated interstitial lung disease, approval also requires:

- You have Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
- You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
- You have a baseline (before treatment) forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40 percent of predicted value
- You do NOT have other causes of interstitial lung disease (ILD: a type of lung condition) (such as heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors [class of blood pressure medications], recurrent aspiration [inhaling] such as from GERD [acid reflux], pulmonary vascular disease [affecting blood vessels in lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease [MCTD])

If you have chronic fibrosing interstitial lung disease with a progressive phenotype, approval also requires:

- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
- Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities [additional health conditions] such as infection, heart failure)
- You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing) (such as reticular abnormality [a specific pattern on imaging studies] with traction bronchiectasis [a condition where your lungs' airway becomes damaged, widened, and thickened] with or without honeycombing)
- You will NOT use Ofev concurrently (at the same time) with Esbriet

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NINTEDANIB

RENEWAL CRITERIA

Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
- Chronic fibrosing interstitial lung disease with a progressive phenotype (PF-ILD: a type of lung condition with scarring of the lungs caused by different underlying diseases/conditions that worsen over time)

If you have idiopathic pulmonary fibrosis or chronic fibrosing interstitial lung disease with a progressive phenotype, renewal also requires:
- You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
- You will NOT use Ofev concurrently (at the same time) with Esbriet

If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
- You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

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NIPOCALIMAB-AAHU

Generic	Brand				
NIPOCALIMAB-AAHU	IMAAVY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NIPOCALIMAB-AAHU (Imaavy)** requires the following rule(s) be met for approval:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. Your diagnosis is confirmed by a positive serologic test (a type of blood test) for anti-acetylcholine receptor antibody (AChR-Ab+: an indicator of myasthenia gravis) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+: an indicator of myasthenia gravis)
E. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
F. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE corticosteroid (such as prednisone)
G. You will NOT use Imaavy concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
H. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medications: TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
    2. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)
I. If you are 18 years of age or older, approval also requires:
    1. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

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NIPOCALIMAB-AAHU

RENEWAL CRITERIA

Our guideline named **NIPOCALIMAB-AAHU (Imaavy)** requires the following rule(s) be met for renewal:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You have shown a clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
C. You will NOT use Imaavy concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

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Effective: 05/28/26

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NIRAPARIB

Generic	Brand				
NIRAPARIB TOSYLATE	ZEJULA				

GUIDELINES FOR USE

Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

You have advanced (has spread to other parts of the body) or recurrent (has returned) epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)

If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

- You are 18 years of age or older
- You are in complete or partial response (cancer is not detectable or has partly responded to treatment but still did not go away) to first-line platinum-based chemotherapy (such as cisplatin, carboplatin)
- Your cancer is associated with homologous recombination deficiency (HRD: a type of gene mutation)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation (a type of gene mutation), and/or genomic instability (high rate of gene mutation)

If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

- You are 18 years of age or older
- Your cancer has a deleterious or suspected deleterious germline BRCA-mutation (gBRCAmut: a type of gene mutation [abnormal change]) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Zejula
- You have completed at least TWO lines of platinum-based chemotherapy (such as cisplatin, carboplatin)
- You are in complete or partial response (cancer is not detectable or has partly responded to treatment but still did not go away) to platinum-based chemotherapy (such as cisplatin, carboplatin)
- Zejula will be started no later than 8 weeks after your most recent platinum-containing regimen (such as cisplatin, carboplatin)

Effective: 08/04/25

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NIRAPARIB-ABIRATERONE

Generic	Brand				
NIRAPARIB-ABIRATERONE	AKEEGA				

GUIDELINES FOR USE

Our guideline named **NIRAPARIB-ABIRATERONE (Akeega)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
- Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

If you have metastatic castration-resistant prostate cancer, approval also requires:
- Your cancer has a deleterious (harmful) or suspected deleterious BRCA mutation (BRCAm: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
- Akeega will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
- You meet ONE of the following:
  - You had a bilateral orchiectomy (both testicles have been surgically removed)
  - You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
  - Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If you have metastatic castration-sensitive prostate cancer, approval also requires:
- Your cancer has a deleterious (harmful) or suspected deleterious BRCA2 mutation (BRCA2m: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
- Akeega will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
- You meet ONE of the following:
  - You had a bilateral orchiectomy (both testicles have been surgically removed)
  - You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
  - Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

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NIROGACESTAT

Generic	Brand				
NIROGACESTAT HYDROBROMIDE	OGSIVEO				

GUIDELINES FOR USE

Our guideline named **NIROGACESTAT (Ogsiveo)** requires the following rule(s) be met for approval:
You have progressing desmoid tumors (noncancerous growths in the connective tissue)
You are 18 years of age or older
You require systemic treatment (treatment that targets the entire body)

Effective: 02/01/26

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NIRSEVIMAB-ALIP (NSA)

Generic	Brand				
NIRSEVIMAB-ALIP	BEYFORTUS				

GUIDELINES FOR USE

Our guideline named **NIRSEVIMAB-ALIP (Beyfortus)** requires the following rule(s) be met for approval:

Beyfortus will be used for the prevention of respiratory syncytial virus (RSV: a type of lung and respiratory tract infection)

You meet ONE of the following:

- You are less than 12 months of age (neonate or infant), and you were born during or are entering your first RSV season (period of increased rate of infection)
- You are 12 to 24 months of age and are vulnerable to (at risk of) severe RSV disease

You have NOT completed a course of Synagis (palivizumab) within this RSV season or you have not received a dose of Synagis in the past 30 days, AND you will not receive further doses of Synagis within this RSV season

You have not received more than 2 doses of Beyfortus in your lifetime, unless you have undergone or will undergo a cardiac surgery with cardiopulmonary bypass (a type of heart and lung surgery)

Requests for zero dollar cost share also requires that you are 19 months of age or younger

Effective: 03/03/25

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NITISINONE

Generic	Brand				
NITISINONE	ORFADIN, NITYR, NITISINONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:
You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder)
You have elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation (abnormal change) in the fumarylacetoacetate hydrolase gene
Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
If you are requesting Nityr tablets; brand Orfadin capsules; or Orfadin oral suspension, approval also requires:
You have tried or have a contraindication to (harmful for you to use) generic nitisinone capsules

RENEWAL CRITERIA

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:
You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder)
Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

Effective: 08/04/25

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NITISINONE-HARLIKU

Generic	Brand				
NITISINONE	HARLIKU				

GUIDELINES FOR USE

Our guideline named **NITISINONE-HARLIKU** requires the following rule(s) be met for approval:
You have alkaptonuria (AKU: a type of rare genetic disorder)
You are 18 years of age or older
Harliku will be used to reduce the level of urine homogentisic acid (HGA) (a type of lab test)

Effective: 08/04/25

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NITROFURANTOIN SUSPENSION

Generic	Brand				
NITROFURANTOIN	FURADANTIN, NITROFURANTOIN				

GUIDELINES FOR USE

Our guideline named **NITROFURANTOIN (Furadantin)** requires the following rule(s) be met for approval:

A. You have a urinary tract infection (UTI: a type of infection)
B. Your infection is caused by susceptible (can be treated with the drug) strains of *Escherichia coli, enterococci, Staphylococcus aureus, Klebsiella* or *Enterobacter* species (types of bacteria)
C. You have a contraindication to (harmful for you to use) or are not able to swallow nitrofurantoin capsules

Effective: 07/01/26

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NIVOLUMAB

Generic	Brand				
NIVOLUMAB	OPDIVO				

GUIDELINES FOR USE

Our guideline named **NIVOLUMAB (Opdivo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Stage IIB, IIC, III, or IV melanoma (a type of skin cancer)
   3. Resectable (node positive or tumor is 4 cm or greater) non-small cell lung cancer (NSCLC) (a type of lung cancer that can be removed by surgery)
   4. Metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
   5. Recurrent non-small cell lung cancer (NSCLC) (a type of lung cancer that has returned)
   6. Unresectable malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery)
   7. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   8. Classical Hodgkin lymphoma (cHL: a type of blood cancer)
   9. Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN: type of head/neck cancer that has returned or spread to other parts of the body)
   10. Urothelial carcinoma (UC: urinary system cancer)
   11. Unresectable or metastatic urothelial carcinoma (urinary system cancer that cannot be removed by surgery or has spread to other parts of the body)
   12. Locally advanced or metastatic urothelial carcinoma (urinary system cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)
   13. Colorectal cancer (a type of digestive cancer)
   14. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
   15. Completely resected esophageal or gastroesophageal junction cancer (types of digestive system cancer that has been removed by surgery)
   16. Unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC: type of digestive system cancer that cannot be removed by surgery, and has returned or has spread to other parts of the body)
   17. Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC: type of digestive system cancer that cannot be removed by surgery and has spread to other parts of the body)
   18. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (types of digestive system cancer that has spread to other parts of the body)

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You are 12 years of age or older
   2. Opdivo will be used alone OR in combination with Yervoy (ipilimumab)
   3. Opdivo will NOT be used concurrently (at the same time) with a targeted therapy (BRAF inhibitors [such as Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [such as Mekinist (trametinib)], and NTRK inhibitors [such as Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

C. **If you have stage IIB, IIC, III, or IV melanoma, approval also requires:**
   1. You are 12 years of age or older
   2. You have undergone complete resection (completely removed by surgery)
   3. Opdivo will be used as an adjuvant (add-on) treatment

D. **If you have resectable (node positive or tumor is 4 cm or greater) non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Opdivo will be used in combination with platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment (given before main treatment) only
      b. Your cancer has NO known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements (type of gene mutation); AND Opdivo will be used in combination with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment), OR as a single medication as adjuvant (add-on) treatment after surgery and prior use with platinum-doublet chemotherapy as neoadjuvant treatment

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GUIDELINES FOR USE (CONTINUED)

E. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your tumors have programmed death-ligand 1 (PD-L1: a type of protein [of at least 1 percent]) as determined by a Food and Drug Administration (FDA)-approved test; your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene); AND Opdivo will be used in combination with Yervoy (ipilimumab)
      b. Your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene) AND Opdivo will be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)
      c. Your disease has worsened while on or after platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin), and you meet ONE of the following:
         i. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic tumor aberrations (types of abnormal gene)
         ii. Your tumor has an ALK mutation, and your disease has worsened after treatment with an FDA-approved ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
         iii. Your tumor has an EGFR mutation, and your disease has worsened after treatment with an FDA-approved EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

F. **If you have recurrent non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene)
   3. Opdivo will be used in combination with Yervoy (ipilimumab) AND 2 cycles of platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)

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GUIDELINES FOR USE (CONTINUED)

G. **If you have unresectable malignant pleural mesothelioma, approval also requires:**
   1. You are 18 years of age or older
   2. Opdivo will be used in combination with Yervoy (ipilimumab)

H. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have intermediate or poor risk disease AND Opdivo will used in combination with Yervoy (ipilimumab)
      b. Opdivo will be used in combination with Cabometyx (cabozantinib)
      c. You have received prior anti-angiogenic therapy (medication that stop tumors from growing their own blood vessels such as Sutent [sunitinib], Votrient [pazopanib], Cabometyx [cabozantinib])

I. **If you have classical Hodgkin lymphoma, approval also requires ONE of the following:**
   1. If your disease has been previously treated, you meet ALL of the following:
      a. You are 18 years of age or older
      b. Your disease has relapsed (returned) or worsened after receiving ONE of the following:
         i. Autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells) and Adcetris (brentuximab vedotin)
         ii. Three or more lines of systemic therapy (treatment that targets the entire body) that includes autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)
   2. If your disease has NOT been previously treated, you meet ALL of the following:
      a. You are 12 years of age or older
      b. Your disease is Stage III or IV
      c. Opdivo will be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD)

J. **If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
   1. You are 18 years of age or older
   2. Your disease has worsened on or after treatment with a platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

K. **If you have urothelial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Opdivo will be used as an adjuvant (add-on) treatment
   3. You are at high risk of recurrence (disease returning) after undergoing radical resection (tumor removal) of urothelial carcinoma

L. **If you have unresectable or metastatic urothelial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Opdivo in combination with cisplatin and gemcitabine

M. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your disease has worsened during or after platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
      b. Your disease has worsened within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

N. **If you have colorectal cancer, approval also requires:**
   1. You are 12 years of age or older
   2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)
   3. You meet ONE of the following:
      a. Your cancer is unresectable (cannot be removed by surgery); AND Opdivo will be used in combination with Yervoy (ipilimumab)
      b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
         i. Opdivo will be used in combination with Yervoy (ipilimumab)
         ii. Opdivo will be used as a single medication; AND your disease has worsened after treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

O. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires ONE of the following:**
   1. You will be using Opdivo in combination with Yervoy (ipilimumab) as first-line treatment
   2. You will be using Opdivo in combination with Yervoy (ipilimumab), AND you have been previously treated with Nexavar (sorafenib)

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GUIDELINES FOR USE (CONTINUED)

P. **If you have completely resected esophageal or gastroesophageal junction cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Opdivo will be used as an adjuvant (add-on) treatment
   3. You have a residual pathologic disease (disease is still present) and have received neoadjuvant chemoradiotherapy (CRT) (a type of cancer treatment given before surgery)

Q. **If you have unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously received treatment with fluoropyrimidine- and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

R. **If you have unresectable advanced or metastatic esophageal squamous cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You will be using Opdivo in combination with fluoropyrimidine- and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
      b. You will be using Opdivo in combination with Yervoy (ipilimumab)

S. **If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Opdivo in combination with fluoropyrimidine and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

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NIVOLUMAB-HYALURONIDASE-NVHY

Generic	Brand				
NIVOLUMAB-HYALURONIDASE-NVHY	OPDIVO QVANTIG				

GUIDELINES FOR USE

Our guideline named **NIVOLUMAB-HYALURONIDASE-NVHY (Opdivo Qvantig)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Advanced renal cell carcinoma (RCC) (a type of kidney cancer)
- Melanoma (a type of skin cancer)
- Non-small cell lung cancer (NSCLC) (a type of lung cancer)
- Metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
- Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (a type of head/neck cancer that has returned or has spread to other parts of the body)
- Urothelial carcinoma (UC: urinary system cancer)
- Colorectal cancer (CRC) (a type of digestive cancer)
- Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)
- Esophageal or gastroesophageal junction cancer (types of digestive system cancer)
- Esophageal squamous cell carcinoma (ESCC) (a type of digestive system cancer)
- Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (types of digestive system cancer that has spread to other parts of the body)

If you have advanced renal cell carcinoma, approval also requires:

- You are 18 years of age or older
- You meet ONE of the following:
  - You have intermediate or poor risk disease, and Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
  - Opdivo Qvantig will be used in combination with Cabometyx (cabozantinib)
  - You have received prior anti-angiogenic therapy (a type of medication that stops tumors from growing new blood vessels, such as Sutent [sunitinib], Votrient [pazopanib])

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NIVOLUMAB-HYALURONIDASE-NVHY

GUIDELINES FOR USE (CONTINUED)

If you have melanoma, approval also requires:
- You are 12 years of age or older
- You meet ONE of the following:
  - Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body)
  - Your cancer is stage IIB, IIC, III, or IV; you have undergone complete resection (removal by surgery); and Opdivo Qvantig will be used as an adjuvant (add-on) treatment

If you have non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer is resectable (node positive or tumor is at least 4 cm) (can be removed by surgery)
- You meet ONE of the following:
  - Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment (given before main treatment)
  - Your cancer has no known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements (type of gene mutation), and you meet ONE of the following:
    - Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment)
    - Opdivo Qvantig will be used alone as adjuvant (add-on) treatment after surgical resection (removal by surgery) and prior use with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment)

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GUIDELINES FOR USE (CONTINUED)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your disease has worsened while on or after platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin), and you meet ONE of the following:
  - Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic aberrations (types of abnormal gene)
  - Your tumor has an epidermal growth factor receptor (EGFR: type of protein) mutation (abnormal change in a type of gene), and your disease has worsened after treatment with a Food and Drug Administration (FDA)-approved EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
  - Your tumor has an anaplastic lymphoma kinase (ALK: type of enzyme) mutation (abnormal change in a type of gene), and your disease has worsened after treatment with a Food and Drug Administration (FDA)-approved ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])

If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
- You are 18 years of age or older
- Your disease has worsened while on or after treatment with a platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

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GUIDELINES FOR USE (CONTINUED)

If you have urothelial carcinoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You are at high risk of recurrence (disease returning) after undergoing radical resection (tumor removal) of urothelial carcinoma (UC: urinary system cancer), and Opdivo Qvantig will be used as an adjuvant (add-on) treatment
  - Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body), and Opdivo Qvantig will be used in combination with cisplatin and gemcitabine
  - Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), and you meet ONE of the following:
    - Your disease has worsened during or following platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
    - Your disease has worsened within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

If you have colorectal cancer, approval also requires:
- You are 12 years of age or older
- Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)
- You meet ONE of the following:
  - You have metastatic cancer (cancer that has spread to other parts of the body) and meet ONE of the following:
    - Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
    - Your disease has worsened after treatment with a fluoropyrimidine (a type of cancer treatment, such as fluorouracil, capecitabine), oxaliplatin, and irinotecan
  - You have unresectable cancer (cancer that cannot be removed by surgery) and Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- You are 18 years of age or older
- Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

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NIVOLUMAB-HYALURONIDASE-NVHY

GUIDELINES FOR USE (CONTINUED)

If you have esophageal or gastroesophageal junction cancer, approval also requires:
- You are 18 years of age or older
- You have undergone complete resection (removal by surgery)
- Opdivo Qvantig will be used as an adjuvant (add-on) treatment
- You have a residual pathologic disease (disease is still present)
- You have received neoadjuvant chemoradiotherapy (CRT) (a type of cancer treatment given before surgery)

If you have esophageal squamous cell carcinoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Your cancer is unresectable (cannot be removed by surgery) advanced or metastatic (has spread to other parts of the body); Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%)
  - Your cancer is unresectable (cannot be removed by surgery) advanced, recurrent (has returned) or metastatic (has spread to other parts of the body), AND you have previously received treatment with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma, approval also requires:
- You are 18 years of age or older
- Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
- Your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%)

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NIVOLUMAB-RELATLIMAB-RMBW (NSA)

Generic	Brand				
NIVOLUMAB-RELATLIMAB-RMBW	OPDUALAG				

GUIDELINES FOR USE

Our guideline named **NIVOLUMAB-RELATLIMAB-RMBW (Opdualag)** requires the following rule(s) be met for approval:

You have unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)

You are 12 years of age or older

Effective: 07/01/22

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NOGAPENDEKIN ALFA (NSA)

Generic	Brand				
NOGAPENDEKIN ALFA INBAKICEPT-PMLN	ANKTIVA				

GUIDELINES FOR USE

Our guideline named **NOGAPENDEKIN ALFA (Anktiva)** requires the following rule(s) be met for approval:

You have non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (a type of early stage bladder cancer)

You are 18 years of age or older

Your cancer did not respond to treatment with Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment)

Anktiva will be used together with Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment)

Effective: 05/13/24

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NUSINERSEN (NSA)

Generic	Brand			
NUSINERSEN	SPINRAZA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NUSINERSEN (Spinraza)** requires the following rule(s) be met for approval:

You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)

Your diagnosis of spinal muscular atrophy (SMA) is confirmed by a gene mutation analysis indicating mutations (abnormal changes) or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])

Therapy is prescribed by or in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center

If you are pre-symptomatic (symptoms have not yet appeared), approval also requires:

You have up to (no more than) three copies of the survival motor neuron 2 (SMN2: type of protein in spinal cord) gene based on screening that was done when you were a newborn

If you are symptomatic (symptoms have appeared), approval also requires:

The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age

You had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist

If you previously had gene therapy, you experienced a less than expected clinical benefit with gene therapy

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NUSINERSEN (NSA)

RENEWAL CRITERIA

Our guideline named **NUSINERSEN (Spinraza)** requires the following rule(s) be met for renewal:
You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
You meet ONE of the following:
- You have improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
- You have improved, maintained, or demonstrated a less than expected decline in other muscle function (such as pulmonary [lung/breathing] function)

Effective: 07/01/24

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OBETICHOLIC ACID

Generic	Brand				
OBETICHOLIC ACID	OCALIVA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210 if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)
B. You are 18 years of age or older
C. You do not have cirrhosis (liver damage and scarring) OR you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)
D. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)
E. You do NOT have complete biliary obstruction (blockage of bile ducts)
F. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])
G. You meet ONE of the following:
   1. Ocaliva will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Ocaliva will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

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OBETICHOLIC ACID

RENEWAL CRITERIA

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
B. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Ocaliva
C. You have NOT developed complete biliary obstruction (blockage of bile ducts)
D. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])

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OBINUTUZUMAB

Generic	Brand				
OBINUTUZUMAB	GAZYVA				

GUIDELINES FOR USE

Our guideline named **OBINUTUZUMAB (Gazyva)** requires the following rule(s) be met for approval:

The request is for ONE of the following:
- Chronic lymphocytic leukemia (CLL: a type of blood and bone marrow cancer)
- Follicular lymphoma (FL: a type of cancer with abnormal immune cells)
- Use as a pretreatment prior to initiating Columvi (glofitamab-gxbm)
- Lupus nephritis (a type of immune condition that affects the kidneys)

If you have chronic lymphocytic leukemia, approval also requires:
- You have NOT received previous treatment for chronic lymphocytic leukemia
- Gazyva will be used in combination with Leukeran (chlorambucil)

If you have follicular lymphoma, approval also requires ONE of the following:
- You have relapsed after or are refractory to (disease has returned or is resistant to) a regimen containing rituximab; AND Gazyva will be used in combination with bendamustine for the initial six cycles OR as monotherapy (the only drug used in treatment) thereafter
- Your cancer is stage II bulky, III, or IV; you are 18 years of age or older; you have NOT received previous treatment for stage II bulky, III or IV follicular lymphoma; AND Gazyva will be used in combination with chemotherapy (such as bendamustine; CHOP [cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone]; CVP [cyclophosphamide, vincristine, prednisone or prednisolone]) for the initial six or eight cycles, or as monotherapy (the only drug used in treatment) thereafter
- You have relapsed or refractory follicular lymphoma (disease has returned or is resistant to treatment); AND Gazyva will be used in combination with Brukinsa (zanubrutinib)

If you have lupus nephritis, approval also requires:
- You are 18 years of age or older
- You are receiving standard therapy (such as mycophenolate mofetil and corticosteroids)

Effective: 12/01/25

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OCRELIZUMAB AND OCRELIZUMAB-HYALURONIDASE-OCSQ

Generic	Brand				
OCRELIZUMAB	OCREVUS				
OCRELIZUMAB-HYALURONIDASE-OCSQ	OCREVUS ZUNOVO				

GUIDELINES FOR USE

Our guideline named **OCRELIZUMAB AND OCRELIZUMAB-HYALURONIDASE-OCSQ (Ocrevus, Ocrevus Zunovo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary progressive multiple sclerosis (PPMS: a type of nerve disorder)
   2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   3. Relapsing-remitting multiple sclerosis (MS) (a type of nerve disorder that returns and goes away)

B. **If you have primary progressive multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older

C. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

D. **If you have relapsing-remitting multiple sclerosis, approval also requires:**
   1. The request is for Ocrevus (ocrelizumab)
   2. You meet ONE of the following:
      a. You are 10 to 17 years of age
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

Effective: 06/10/26

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OCTREOTIDE - IM

Generic	Brand				
OCTREOTIDE ACETATE, MI-SPHERES	SANDOSTATIN LAR DEPOT, OCTREOTIDE ACETATE ER				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acromegaly (a type of hormone disorder)
- Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
- Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of tumor that starts from hormone producing cells)

If you have acromegaly, approval also requires:
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- You had an inadequate response (did not work) to surgery or radiotherapy (a type of cancer treatment), OR surgery or radiotherapy is not an option for you
- Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
- You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:
- You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, approval also requires:
- You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

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OCTREOTIDE - IM

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Acromegaly (a type of hormone disorder)
- Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
- Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of tumor that starts from hormone producing cells)

If you have acromegaly, renewal also requires:

- You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
- You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, renewal also requires:

- You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms

If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, renewal also requires:

- You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms

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Effective: 01/01/26

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OCTREOTIDE - ORAL

Generic	Brand				
OCTREOTIDE ACETATE	MYCAPSSA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for approval:
You have acromegaly (a type of hormone disorder)
You have responded to and tolerated treatment with octreotide or lanreotide
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for renewal:
You have acromegaly (a type of hormone disorder)
You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

Effective: 01/01/26

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OCTREOTIDE - SQ

Generic	Brand				
OCTREOTIDE ACETATE	BYNFEZIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a generic octreotide (such as octreotide acetate)
   5. You had an inadequate response (did not work) to or cannot be treated with surgical resection (removal by surgery), pituitary irradiation (radiation therapy directed at the pituitary), and bromocriptine mesylate at maximally tolerated doses

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a generic octreotide (such as octreotide acetate)

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas), approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a generic octreotide (such as octreotide acetate)

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OCTREOTIDE - SQ

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, renewal also requires:**
   1. You have had a reduction, normalization or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   2. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, renewal also requires:**
   1. You have an improvement or sustained remission (reduction or disappearance) of clinical symptoms

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas), renewal also requires:**
   1. You have an improvement or sustained remission (reduction or disappearance) of clinical symptoms

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ODEVIXIBAT

Generic	Brand				
ODEVIXIBAT	BYLVAY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

B. **If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
   2. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])
   3. You meet ONE of the following:
      a. You are 3 months to 11 months of age
      b. You are 12 months of age or older AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Livmarli (maralixibat)

C. **If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:**
   1. You are 12 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
   3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Livmarli (maralixibat)

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ODEVIXIBAT

RENEWAL CRITERIA (CONTINUED)

Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

B. **If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
   2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
   3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

C. **If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:**
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
   2. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

Effective: 07/01/25

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OFATUMUMAB (NSA)

Generic	Brand			
OFATUMUMAB	ARZERRA			

GUIDELINES FOR USE

Our guideline named **OFATUMUMAB (Arzerra)** requires the following rule(s) be met for approval:
You have chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)

If you have previously untreated chronic lymphocytic leukemia, approval also requires:
- You have not received previous treatment for chronic lymphocytic leukemia
- Fludara (fludarabine)-based therapy is considered inappropriate for you
- The requested medication will be used in combination with chlorambucil

If you have relapsed chronic lymphocytic leukemia (type of blood and bone marrow cancer that has returned), approval also requires:
- The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide

If you are requesting extended treatment of chronic lymphocytic leukemia, approval also requires:
- You are in complete or partial response
- You have received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia

If you have refractory chronic lymphocytic leukemia, approval also requires:
- You are refractory (non-responsive) to Fludara (fludarabine) and Campath (alemtuzumab)

Effective: 04/10/21

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OFATUMUMAB-SQ

Generic	Brand				
OFATUMUMAB	KESIMPTA				

GUIDELINES FOR USE

Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

You are 18 years of age or older

Effective: 02/01/26

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OLAPARIB

Generic	Brand				
OLAPARIB	LYNPARZA				

GUIDELINES FOR USE

Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced or recurrent (returning) epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (types of reproductive system cancers)
   2. High risk early breast cancer
   3. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
   5. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
   6. A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   3. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You meet ONE of the following:
      a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation)
      b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

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GUIDELINES FOR USE (CONTINUED)

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You are in complete or partial response to platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. Lynparza will be used as monotherapy (used alone)

D. **If you have high risk early breast cancer, approval also requires:**
   1. Lynparza will be used as adjuvant (add-on) treatment
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before the main treatment or as add-on therapy such as doxorubicin, paclitaxel)

E. **If you have metastatic breast cancer, approval also requires:**
   1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before the main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
   4. You meet ONE of the following:
      a. You do not have hormone receptor (HR)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer and have been treated with prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]), or endocrine therapy is considered inappropriate for you

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (such as paclitaxel, docetaxel, cisplatin, carboplatin)

G. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer has worsened following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa or Zytiga) AND has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
      b. Lynparza will be used in combination with abiraterone (Yonsa or Zytiga) and with prednisone or prednisolone AND your cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

Effective: 02/09/26

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OLEZARSEN

Generic	Brand				
OLEZARSEN SODIUM	TRYNGOLZA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OLEZARSEN (Tryngolza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   2. Severe hypertriglyceridemia (high levels of fat in the blood)

B. **If you have familial chylomicronemia syndrome, approval also requires:**
   1. You are 18 years of age or older
   2. You will use Tryngolza as an adjunct (add-on) therapy to diet
   3. You will NOT use Tryngolza concurrently (at the same time) with another medication (such as Redemplo [plozasiran]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   4. Your familial chylomicronemia syndrome (FCS: a type of rare genetic condition) has been confirmed with ONE of the following:
      a. Genetic testing (a type of lab test)
      b. History of fasting triglycerides (a type of fat) of at least 1000 mg/dL on repeated testing (for at least 3 prior occasions) AND a history of recurrent acute pancreatitis (short-term inflammation of the pancreas) that is not caused by alcohol or cholelithiasis (hard, pebble-like stones that form inside gallbladder), a history of hospitalization for severe abdominal pain without other explainable cause, or a family history of hypertriglyceridemia-induced pancreatitis (high levels of fat in the blood due to pancreas inflammation)

C. **If you have severe hypertriglyceridemia, approval also requires:**
   1. You are 18 years of age or older
   2. You are adhering to (keeping up with) or have previously tried guideline-recommended lifestyle interventions for triglyceride (a type of fat) reduction (decrease), including dietary modifications (changes) and physical activity when clinically appropriate and feasible (doable)
   3. You have a baseline (before treatment) fasting triglyceride (a type of lab test) level of at least 500 mg/dL
   4. You have tried or have a contraindication to (harmful for you to use) TWO clinical standard of care triglyceride (a type of fat) lowering therapies (such as Vascepa [icosapent ethyl], Lovaza [omega-3 acid ethyl esters], Lopid [gemfibrozil], fenofibrate, statin [such as atorvastatin, simvastatin, rosuvastatin])

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OLEZARSEN

RENEWAL CRITERIA

Our guideline named **OLEZARSEN (Tryngolza)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   2. Severe hypertriglyceridemia (high levels of fat in the blood)

B. **If you have familial chylomicronemia syndrome, renewal also requires:**
   1. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels
   2. You will NOT use Tryngolza concurrently (at the same time) with another medication (such as Redemplo [plozasiran]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)

C. **If you have severe hypertriglyceridemia, renewal also requires:**
   1. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels or acute pancreatitis (short-term inflammation of the pancreas) events

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Effective: 08/28/26

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OLUTASIDENIB

Generic	Brand				
OLUTASIDENIB	REZLIDHIA				

GUIDELINES FOR USE

Our guideline named **OLUTASIDENIB (Rezlidhia)** requires the following rule(s) be met for approval:

You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)

You are 18 years of age or older

You have a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation, as detected by a Food and Drug Administration (FDA)-approved test

Effective: 02/01/26

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OLIPUDASE ALFA-RPCP (NSA)

Generic	Brand				
OLIPUDASE ALFA-RPCP	XENPOZYME				

GUIDELINES FOR USE

Our guideline named **OLIPUDASE ALFA-RPCP (Xenpozyme)** requires the following rule(s) be met for approval:

You have acid sphingomyelinase deficiency (ASMD: a type of rare genetic disorder that affects the body's ability to break down fat)

You have non-central nervous system manifestations (affected organs are not in the brain or spinal cord) of ASMD

You have baseline alanine aminotransferase (ALT: a type of liver enzyme test) and aspartate aminotransferase (AST: a type of liver enzyme test) levels within 1 month of Xenpozyme start date

Effective: 01/01/23

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OMACETAXINE

Generic	Brand				
OMACETAXINE MEPESUCCINATE	SYNRIBO				

GUIDELINES FOR USE

Our guideline named **OMACETAXINE (Synribo)** requires the following rule(s) be met for approval:

You have chronic or accelerated phase chronic myeloid leukemia (CML: a type of blood cell cancer)

You are 18 years of age or older

You had a resistance (medication does not work as well) or intolerance (side effect) to at least TWO tyrosine kinase inhibitors (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib], Bosulif [bosutinib], Iclusig [ponatinib])

Effective: 03/04/26

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OMADACYCLINE

Generic	Brand				
OMADACYCLINE TOSYLATE	NUZYRA				

GUIDELINES FOR USE

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Community-acquired bacterial pneumonia (CABP: a type of lung infection)
- Acute bacterial skin or skin structure infection (ABSSSI: a type of skin condition)

If you have community-acquired bacterial pneumonia, approval also requires:

- You are 18 years of age or older
- Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
- You meet ONE of the following:
  - Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
  - Therapy is prescribed by or in consultation with an infectious disease (ID) specialist (a doctor who specializes in the treatment of infections)
  - Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
    - The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
    - Nuzyra will work against the bacteria
  - If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

If you have an acute bacterial skin or skin structure infection (ABSSSI), approval also requires:

- You are 18 years of age or older
- Your infection is caused by any of the following microorganisms (bacteria that the medication can work on): *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (*includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*
- You meet ONE of the following:
  - Therapy is prescribed by or in consultation with an infectious disease (ID) specialist (a doctor who specializes in the treatment of infections)
  - Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
    - The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
    - Nuzyra will work against the bacteria
  - If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO standard of care medications for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

Effective: 10/01/25

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OMALIZUMAB

Generic	Brand				
OMALIZUMAB	XOLAIR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a baseline IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   5. Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   6. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

7. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
   4. You have inadequately controlled disease
   5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
   6. Xolair will be used as add-on maintenance treatment (taken on a regular basis)
   7. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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INITIAL CRITERIA (CONTINUED)

D. **If you have an IgE-mediated food allergy, approval also requires:**
   1. You are 1 year of age or older
   2. You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Xolair
   3. You have an IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   4. You have an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
   5. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
   6. You have an active prescription for epinephrine auto-injector/injection while on Xolair
   7. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

E. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
   4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), the clinical standard of care medication at four times the maximally labeled dose: a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
   5. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

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OMALIZUMAB

RENEWAL CRITERIA

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]), or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Xolair)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline (before starting Xolair)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have an IgE-mediated food allergy, renewal also requires:**
   1. You have persistent IgE-mediated food allergy
   2. You have an active prescription for epinephrine auto-injector/injection while on Xolair
   3. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

E. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:**
   1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
   3. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

Effective: 06/03/26

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OMALIZUMAB-IGEC

Generic	Brand				
OMALIZUMAB-IGEC	OMLYCLO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OMALIZUMAB-IGEC (Omlyclo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a baseline IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   5. Omlyclo will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   6. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma (a type of lung condition)

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

7. You meet ONE of the following:
   a. You have experienced at least ONE asthma (a type of lung condition) exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
   4. You have inadequately controlled disease
   5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
   6. Omlyclo will be used as add-on maintenance treatment (taken on a regular basis)
   7. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus ways with small growths in the nose)

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

D. **If you have an IgE-mediated food allergy, approval also requires:**
   1. You are 1 year of age or older
   2. You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Omlyclo
   3. You have an IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   4. You have an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
   5. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
   6. You have an active prescription for epinephrine auto-injector/injection while on Omlyclo
   7. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy (body's reaction to a food allergy)

E. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
   4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), the clinical standard of care medication at four times the maximally labeled dose: a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
   5. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) (severe itching with unknown cause)

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OMALIZUMAB-IGEC

RENEWAL CRITERIA

Our guideline named **OMALIZUMAB-IGEC (Omlyclo)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]), or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma (a type of lung condition)
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma (a type of lung condition) exacerbations (worsening of symptoms) from baseline (before starting Omlyclo)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in percent predicted FEV1 (type of lung test) from pre-treatment baseline (before starting Omlyclo)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (before starting Omlyclo) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus ways with small growths in the nose)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have an IgE-mediated food allergy, renewal also requires:**
   1. You have persistent IgE-mediated food allergy (body's reaction to a food allergy)
   2. You have an active prescription for epinephrine auto-injector/injection while on Omlyclo
   3. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy (body's reaction to a food allergy)

E. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:**
   1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
   3. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) (severe itching with unknown cause)

Effective: 08/22/26

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OMAVELOXOLONE

Generic	Brand				
OMAVELOXOLONE	SKYCLARYS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for approval:
You have Friedreich's ataxia (a type of nervous system and movement disorder)
You are 16 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
Your diagnosis is confirmed by genetic testing (homozygous for guanine-adenine-adenine [GAA] repeat expansion in intron-1 of frataxin [FXN] gene) (a type of gene mutation)

RENEWAL CRITERIA

Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for renewal:
You have Friedreich's ataxia (a type of nervous system and movement disorder)

Effective: 10/01/25

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OMEPRAZOLE-SODIUM BICARBONATE

Generic	Brand				
OMEPRAZOLE/ SODIUM BICARBONATE	KONVOMEP				
	ZEGERID, OMEPRAZOLE-SODIUM BICARBONATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OMEPRAZOLE-SODIUM BICARBONATE (Konvomep, Zegerid)** requires the following rule(s) be met for approval:
You meet ONE of the following:

If you are 1 month to 11 years of age, approval also requires:
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic esomeprazole packets

If you are 12 years of age or older, approval also requires:
- You have a contraindication to (harmful for you to use) OR you are unable to swallow the tablet/capsule formulation of omeprazole, pantoprazole, esomeprazole, or lansoprazole
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic esomeprazole packets

RENEWAL CRITERIA

NOTE: For the diagnosis of H. pylori eradication, please refer to the Initial Criteria section.

Our guideline named **OMEPRAZOLE-SODIUM BICARBONATE (Konvomep, Zegerid)** requires the following rule(s) be met for renewal:
You have had clinical benefit (medication worked)
You require continued therapy of the requested medication

Effective: 03/04/26

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OMIDUBICEL-ONLV

Generic	Brand				
OMIDUBICEL-ONLV	OMISIRGE				

GUIDELINES FOR USE

Our guideline named **OMIDUBICEL-ONLV (Omisirge)** requires the following rule(s) be met for approval:

The request is for ONE of the following:

- To reduce the time to neutrophil recovery (lab levels normalize) and the rate of infection and you have a hematologic malignancy (cancer that affects the blood, bone marrow, and lymph nodes)
- Severe aplastic anemia (SAA: a type of blood disorder)

If the request is to reduce the time to neutrophil recovery and the rate of infection, and you have a hematologic malignancy, approval also requires:

- You will be undergoing umbilical cord blood transplantation (type of procedure) following myeloablative conditioning (a type of treatment such as chemotherapy, radiation)
- You are 12 years of age or older

If you have severe aplastic anemia, approval also requires:

- You are 6 years of age or older
- Omisirge will be used after reduced intensity conditioning (a type of treatment to lower the risk of complications)

Effective: 01/12/26

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ONABOTULINUM TOXIN A

Generic	Brand				
ONABOTULINUMTOXINA	BOTOX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ONABOTULINUM TOXIN A (Botox)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Chronic migraine headaches (at least 15 days per month with headaches lasting 4 hours a day or longer)
- Overactive bladder (a type of bladder condition)
- Urinary incontinence (loss of bladder control)
- Neurogenic detrusor overactivity (a type of bladder condition)
- Spasticity (stiffness or tightness of your muscles)
- Cervical dystonia (a type of muscle condition)
- Severe axillary hyperhidrosis (excessive underarm sweating)
- Blepharospasm (a type of eye disease)
- Strabismus (a type of eye condition)

If you have chronic migraine headaches (at least 15 days per month with headaches lasting 4 hours a day or longer), approval also requires:

- You are 18 years of age or older
- Botox is prescribed for the prophylaxis (prevention) of headaches
- You have tried TWO of the following migraine (a type of headache) prevention treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, metoprolol

If you have overactive bladder, approval also requires:

- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, Sanctura)

(Initial criteria continued on next page)

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ONABOTULINUM TOXIN A

INITIAL CRITERIA (CONTINUED)

If you have urinary incontinence, approval also requires:
- You are 18 years of age or older
- You have detrusor (bladder muscle) overactivity associated with a neurologic (nervous system) condition (such as a spinal cord injury [SCI], multiple sclerosis [MS: a type of nerve disorder])
- You have tried or have a contraindication to (harmful for you to use) an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, Sanctura)

If you have neurogenic detrusor overactivity, approval also requires:
- You are 5 years of age or older
- You did not have an adequate response (medication did not work) or you are not able to take anticholinergic medications (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura)

If you have spasticity, approval also requires:
- You are 2 years of age or older

If you have cervical dystonia, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

If you have severe axillary hyperhidrosis, approval also requires:
- You are 18 years of age or older

If you have blepharospasm, approval also requires:
- You are 12 years of age or older

If you have strabismus, approval also requires:
- You are 12 years of age or older

NOTE: This medication will not be approved for a cosmetic indication (for example wrinkles - glabellar [between the eyebrows] lines, lateral canthal [outer corner of the eyes] lines, forehead lines).

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ONABOTULINUM TOXIN A

RENEWAL CRITERIA

NOTE: For diagnoses other than migraines, please refer to the Initial Criteria section.

Our guideline named **ONABOTULINUM TOXIN A (Botox)** requires the following rule(s) be met for renewal:

You have chronic migraine headaches (at least 15 days per month with headaches lasting 4 hours a day or longer)

You have experienced ONE of the following:

- A reduction in migraine (a type of headache) or headache frequency of at least 2 days per month
- A reduction in migraine (a type of headache) severity
- A reduction in migraine (a type of headache) duration (length)

NOTE: This medication will not be approved for a cosmetic indication (such as wrinkles - glabellar lines [between the eyebrows], lateral canthal [outer corner of eye] lines, forehead lines).

Effective: 01/01/26

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OPICAPONE

Generic	Brand				
OPICAPONE	ONGENTYS				

GUIDELINES FOR USE

Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:
You have Parkinson's disease (PD: a type of movement disorder)
You are 18 years of age or older
You are experiencing 'OFF' episodes (period of symptoms in between doses)
You will also be treated with carbidopa/levodopa (such as Sinemet, Sinemet Controlled Release [CR], Parcopa)
You have tried, failed, or have a contraindication to (harmful for you to use) TWO Parkinson's disease medications from TWO different classes of medications:
Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
Adenosine receptor antagonist A2A (such as istradefylline)
Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

Effective: 02/01/26

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

Generic	Brand				
N/A	N/A				

GUIDELINES FOR USE

Our guideline named **OPIOID-ANTIPSYCHOTIC CONCURRENT USE** allows an approval for use of an opioid with an antipsychotic medication (type of mental health drug) together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the use of an opioid and an antipsychotic medication together is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Effective: 05/28/26

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OPIOID-BENZODIAZEPINE CONCURRENT USE

Generic	Brand				
N/A	N/A				

GUIDELINES FOR USE

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of use of an opioid with a benzodiazepine together when ONE of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor agrees to proceed with the concurrent use (at the same time) of an opioid and a benzodiazepine for a clinically appropriate indication (reason)
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Effective: 05/28/26

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OPIOID-BUPRENORPHINE CONCURRENT USE

Generic	Brand				
N/A	N/A				

GUIDELINES FOR USE

Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid with buprenorphine or a buprenorphine-containing agent together when ONE of the following rule(s) is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended
G. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Effective: 05/28/26

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OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

A claim for a pain medication will be denied when there are two or more providers prescribing opioid medications for a patient who is receiving a high quantity of these agents. Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will allow you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
   1. You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
   2. You are enrolled in a hospice (end of life care)
   3. You are a resident of a long-term care facility or intermediate care for intellectually disabled
   4. You have sickle cell disease (a type of blood disorder)
   5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

B. Your prescriber is aware that there is more than one provider prescribing opiates for you, AND you meet **TWO** of the following:
   1. Your current level of opioid use is necessary and required for your level of pain management needed
   2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   3. You have a pain contract in place
   4. You do NOT have a history of substance abuse or addiction
   5. Your prescriber has committed to monitoring the state's Prescription Monitoring Program to make sure your controlled substance history is consistent with prescribing record

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OPIOID LONG-ACTING DUPLICATIVE THERAPY

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID LONG ACTING DUPLICATIVE THERAPY** allows approval of the requested drug taken together with other long-acting opioid drug(s) from different prescribers when ONE of the following conditions are met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that they are aware that you are concurrently receiving more than one long-acting opioid medication
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

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OPIOID-NAIVE CUMULATIVE DOSING (ONCD)

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID-NAIVE CUMULATIVE DOSING** allows approval of a higher quantity of an opioid medication if at least ONE of the following conditions is met:

- You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
- You are enrolled in hospice (end of life care)
- You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
- You have sickle cell disease (a type of blood disorder)
- You are not opioid naive (you have been consistently using opioid pain medications)
- You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

If none of these conditions apply, BOTH of the following criteria must be met:

- The provider has indicated that your current level of opioid utilization (use) is necessary and required for the level of pain management needed
- The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

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OPIOID-NAIVE DAY SUPPLY LIMITATION

Generic	Brand				
N/A	N/A				

GUIDELINES FOR USE

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for a longer day supply when you meet at least **ONE** of the following conditions:

A. You are enrolled in hospice (end of life care)
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. You are NOT opioid naïve (you have been consistently using opioid pain medications)
F. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary
G. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your doctor if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this medication.

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OPIOID NAIVE FILL LIMIT

Generic	Brand			
N/A	N/A			

GUIDELINES FOR USE

Our guideline named **OPIOID NAIVE FILL LIMIT** allows an approval of the requested drug when it exceeds the fill limit for an initially opioid-naïve patient (those who have not used opioid drugs within the past 60 days) when ONE of the following conditions is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the additional fill of the requested opioid medication is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

Generic	Brand				
OPIOIDS	OPIOIDS				

GUIDELINES FOR USE

Our guideline named **OPIOID SINGLE CLAIM DOSING AT POS** allows for an override of an opioid product equal to or exceeding the soft-stop threshold of **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) at the pharmacy or by a prior authorization. The hard-stop threshold of **[enter hard stop threshold]**-mg morphine milligram equivalent (MME) is not overridable and requires a prior authorization.

An override will be provided if ONE (A or B) of the following rule(s) are met:

A. You meet ONE of the following conditions:
   1. You are receiving treatment for palliative care (treatment for comfort from symptoms)
   2. You have sickle cell disease (a type of blood disorder)
   3. You are enrolled in a hospice (end of life care)
   4. Your doctor is a pain management specialist
   5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

B. Your physician confirms that the requested high dose is considered medically necessary.
   1. If the requested dose is lower than 300 MME, your prescriber must provide a maximum opioid threshold. If your prescriber does not provide a maximum threshold and the request is for an opioid with an MME equal to or exceeding **[enter hard-stop threshold]**-mg morphine milligram equivalent (MME), the claim will be approved up to 25 percent greater than the previously approved MME.
   2. If the requested dose is equal to or greater than 300 MME, approval will be granted if you are stable on the dose.

Please consult your pain management specialist regarding your treatment options.

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OPIOID-SKELETAL MUSCLE RELAXANT CONCURRENT USE

Generic	Brand				
N/A	N/A				

GUIDELINES FOR USE

Our guideline named **OPIOID-SKELETAL MUSCLE RELAXANT CONCURRENT USE** allows an approval for use of an opioid with a skeletal muscle relaxant medication (type of pain medication) together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the use of an opioid and a skeletal muscle relaxant medication together is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

Generic	Brand				
N/A	N/A				

GUIDELINES FOR USE

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you
E. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

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ORFORGLIPRON

Generic	Brand				
ORFORGLIPRON CALCIUM	FOUNDAYO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ORFORGLIPRON (Foundayo)** requires the following rule(s) be met for approval:

A. The request is for weight loss or weight management
B. You are 18 years of age or older
C. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
D. You will NOT use Foundayo concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
E. You meet ONE of the following before starting weight loss therapy:
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
    3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

(Initial criteria continued on next page)

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ORFORGLIPRON

INITIAL CRITERIA (CONTINUED)

4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

RENEWAL CRITERIA

Our guideline named **ORFORGLIPRON (Foundayo)** requires the following rule(s) be met for approval:

A. The request is for weight loss or weight management
B. You meet ONE of the following before starting weight loss therapy:
   1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
   2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
   3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

C. You will NOT use Foundayo concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
D. You have achieved or maintained at least a 5 percent weight loss of baseline (before treatment) body weight

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ORLISTAT

Generic	Brand				
ORLISTAT	XENICAL, ORLISTAT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ORLISTAT (Xenical)** requires the following rule(s) be met for approval:
The request is for weight loss or weight management
You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
You meet ONE of the following before starting weight loss therapy:
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
- You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
- You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
- You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

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ORLISTAT

RENEWAL CRITERIA

Our guideline named **ORLISTAT (Xenical)** requires the following rule(s) be met for renewal:
The request is for weight loss or weight management
If you are younger than 18 years of age, renewal also requires:
- You have achieved or maintained at least a 5% decrease from baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

If you are 18 years of age or older, renewal also requires:
- You meet ONE of the following before starting weight loss therapy:
  - You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
  - You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
  - You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
  - You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
- You have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment

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OSILODROSTAT

Generic	Brand				
OSILODROSTAT PHOSPHATE	ISTURISA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:
You have Cushing's syndrome (a type of hormone disorder)
You are 18 years of age or older
Surgery is not an option or has not cured your condition
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: oral ketoconazole, cabergoline

RENEWAL CRITERIA

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:
You have Cushing's syndrome (a type of hormone disorder)
You continue to have improvement of Cushing's disease/Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
You continue to tolerate treatment with Isturisa

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OSIMERTINIB

Generic	Brand				
OSIMERTINIB MESYLATE	TAGRISSO				

GUIDELINES FOR USE

Our guideline named **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Non-small cell lung cancer (NSCLC: a type of lung cancer)
- A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

If you have non-small cell lung cancer, approval also requires:

- You are 18 years of age or older
- You meet ONE of the following:
  - Tagrisso will be used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor), and your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
  - Your cancer is locally advanced and unresectable (stage III) (cancer that has spread to nearby tissue or lymph nodes and cannot be surgically removed), and you meet ALL of the following:
    - Your disease has NOT worsened during or following concurrent (at the same time) or sequential (one after the other) platinum-based (such as cisplatin, carboplatin) chemoradiation therapy (a type of treatment that combines chemotherapy and radiation)
    - Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
  - Your cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
    - Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
    - Your tumor has an epidermal growth factor receptor (EGFR) T790M mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, AND your disease has worsened while on or after EGFR tyrosine kinase-inhibitor therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

(Criteria continued on next page)

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body), and you meet ALL of the following:

Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (such as cisplatin, carboplatin)

Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

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Effective: 02/09/26

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OTESECONAZOLE

Generic	Brand				
OTESECONAZOLE	VIVJOA				

GUIDELINES FOR USE

Our guideline named **OTESECONAZOLE (Vivjoa)** requires the following rule(s) be met for approval:
You have recurrent vulvovaginal candidiasis (RVVC: a repeating vaginal fungal infection)
You are female
You are not able to reproduce, which means you are a biological female and are postmenopausal (after menopause) or you have another reason for permanent infertility (such as tubal ligation [having tubes tied], hysterectomy [removal of the uterus], salpingo-oophorectomy [removal of an ovary and its fallopian tube])
You are NOT currently on ibrexafungerp for RVVC
If you have not previously received Vivjoa, approval also requires:
You had 3 or more episodes of RVVC in the past 12 months
If you have previously received Vivjoa, approval also requires:
You have successfully completed a course of Vivjoa for prevention of RVVC
You are either being treated or have just completed treatment for a new recurrence of VVC

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OXYMETAZOLINE

Generic	Brand				
OXYMETAZOLINE HCL/PF	UPNEEQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for approval:
You have blepharoptosis (drooping of the upper eyelid)
You are 18 years of age or older
Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
You have been evaluated for surgical intervention
You have experienced visual impairment (limited or blocked vision) due to blepharoptosis (drooping of the upper eyelid)
You have tried TWO ophthalmic alpha-adrenergic agonists (such as apraclonidine, tetrahydrozoline, naphazoline)

RENEWAL CRITERIA

Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for renewal:
You have blepharoptosis (drooping of the upper eyelid)
You continue to benefit from Upneeq

Effective: 10/01/25

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OZANIMOD

Generic	Brand				
OZANIMOD HYDROCHLORIDE	ZEPOSIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Tysabri [natalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)
   3. You do NOT have any of the following contraindications to (harmful for you to use) Zeposia:
      a. Within the last 6 months, experienced a myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (TIA: short stroke-like attack), decompensated heart failure (a type of heart condition) requiring hospitalization, or Class III or IV heart failure (a type of heart condition)
      b. A presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)
      c. Severe untreated sleep apnea (a type of sleep condition with difficulty breathing)
      d. Concomitant use (using at the same time) of a monoamine oxidase inhibitor (a type of medication such as selegiline, phenelzine, linezolid)

(Initial criteria continued on next page)

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      g. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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OZANIMOD

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for renewal:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Skyrizi (risankizumab-rzaa)
    3. Tremfya (guselkumab)
    4. Omvoh (mirikizumab-mrkz)
    5. Adalimumab-ryvk/adalimumab-aaty
    6. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
    7. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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PACLITAXEL PROTEIN-BOUND (NSA)

Generic	Brand			
PACLITAXEL PROTEIN-BOUND	ABRAXANE			

GUIDELINES FOR USE

Our guideline named **PACLITAXEL (Abraxane)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:

- Metastatic breast cancer (breast cancer that has spread to other parts of the body)
- Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC: cancer that is in the advanced stage or that has spread to other parts of the body)
- Small Cell Lung Cancer (SCLC)
- Metastatic adenocarcinoma of the pancreas (pancreas cancer that has spread to other parts of the body)

If you have metastatic breast cancer, approval also requires:

- You have tried a chemotherapy regimen (cancer-treating medications) containing an anthracycline (cancer drug such as doxorubicin or epirubicin) or paclitaxel

If you have metastatic adenocarcinoma of the pancreas, approval also requires:

- The requested medication will be used in combination with gemcitabine

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PACRITINIB

Generic	Brand				
PACRITINIB CITRATE	VONJO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for approval:
You have intermediate- or high-risk primary or secondary (post-polycythemia vera [a type of blood cell disorder] or post-essential thrombocythemia [a type of blood cell disorder]) myelofibrosis (MF: a type of blood cancer)
You are 18 years of age or older
You have a platelet count below 50,000/uL

RENEWAL CRITERIA

Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for renewal:
You have intermediate- or high-risk primary or secondary (post-polycythemia vera [a type of blood cell disorder] or post-essential thrombocythemia [a type of blood cell disorder]) myelofibrosis (MF: a type of blood cancer)
You have shown symptom improvement by meeting ONE of the following:
- You have a spleen volume reduction of at least 35% from baseline (before treatment)
- You have at least a 50% reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
- You have at least a 50% reduction in palpable (can be felt by external examination) spleen length

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PALBOCICLIB

Generic	Brand				
PALBOCICLIB	IBRANCE				

GUIDELINES FOR USE

Our guideline named **PALBOCICLIB (Ibrance)** requires the following rule(s) be met for approval:

A. You have breast cancer

B. **If your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, approval also requires ONE of the following:**
   1. Ibrance will be used in combination with an aromatase inhibitor (such as anastrozole, letrozole, exemestane) as initial endocrine (hormone)-based therapy; your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body); and you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
   2. Ibrance will be used in combination with fulvestrant (Faslodex); your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body); your disease has worsened after endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen); and you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
   3. Ibrance will be used in combination with Itovebi (inavolisib) and fulvestrant (Faslodex); your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body); your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test; and you have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)

C. **If your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, approval also requires:**
   1. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   2. Ibrance will be used in combination with trastuzumab (Herceptin or a Food and Drug Administration [FDA]-approved biosimilar) and endocrine (hormone) therapy (such as letrozole, anastrozole, exemestane, fulvestrant) following induction (initial) treatment

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PALIVIZUMAB (NSA)

Generic	Brand			
PALIVIZUMAB	SYNAGIS			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for approval:

A. You have not received Beyfortus (nirsevimab-alip) within this RSV (type of lung and respiratory tract infection) season
B. You are less than 12 months old or less than 24 months at the start of respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season (mid-September to mid-May)
C. **If you are less than 12 months old, you must meet ONE of the following**:
    1. You have chronic lung disease of prematurity (a condition where you were born at less than 32 weeks and required more than 21% of additional oxygen for at least the first 28 days after birth)
    2. You are profoundly immunocompromised during RSV season (your body cannot fight off infections)
    3. You have received a solid-organ transplant during RSV season
    4. You have congenital (starting from birth) heart disease conditions at birth such as: acyanotic heart disease (blood from the left side to the right side of the heart due to a hole in the heart walls) where you need medication to control chronic heart failure and will require heart surgical procedures; moderate to severe pulmonary hypertension (high blood pressure in the lungs); or cyanotic heart defect (low blood oxygen level) and the requested medication is prescribed by or given in consultation with a pediatric cardiologist (a heart doctor for children)
    5. You have congenital (starting from birth) abnormalities of the lung airways or a neuromuscular (nerve-muscle) disorder that affects respiratory (lung/breathing) secretions
    6. You were born premature at less than 29 weeks (gestational age)
    7. You are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely
D. **If you are less than 24 months old, you must meet ONE of the following:**
    1. You are profoundly immunocompromised during RSV season (a condition where your body cannot fight off infections)
    2. You have chronic lung disease of prematurity and need medical support within 6 months before the start of the second respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season. Medical support includes oxygen, bronchodilator (drug that helps you breathe such as albuterol), diuretic (drug that makes you urinate such as furosemide), or chronic steroid therapy (such as budesonide)
    3. You have received a solid-organ transplant during RSV season

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PALIVIZUMAB (NSA)

RENEWAL CRITERIA

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for renewal:

A. You have not received Beyfortus (nirsevimab-alip) within this RSV (type of lung and respiratory tract infection) season
B. You are under 24 months old
C. You meet **ONE** of the following:
    1. You received cardiopulmonary bypass surgery (type of heart and lung surgery) during respiratory syncytial virus prevention season
    2. This request is for a second year of coverage and you have chronic lung disease of prematurity and need medical support during the 6 months before the start of the second RSV season. Medical support includes oxygen, bronchodilator (drug that helps you breathe such as albuterol), diuretic (drug that makes you urinate such as furosemide), or chronic steroid therapy (such as budesonide)

Effective: 09/11/23

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PALOPEGTERIPARATIDE

Generic	Brand				
PALOPEGTERIPARATIDE	YORVIPATH				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for approval:

A. You have hypoparathyroidism (low levels of parathyroid hormone)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis (balance)
E. You have tried activated vitamin D (such as calcitriol) and calcium

RENEWAL CRITERIA

Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for renewal:

A. You have hypoparathyroidism (low levels of parathyroid hormone)
B. You are independent of or managed on a lowered dose of vitamin D and calcium supplements

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PALOVAROTENE

Generic	Brand				
PALOVAROTENE	SOHONOS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PALOVAROTENE (Sohonos)** requires the following rule(s) be met for approval:

A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
B. Therapy is prescribed by or in consultation with a geneticist (doctor who treats gene disorders), orthopedist (a type of doctor who specializes in bones, joints, muscles, ligaments, tendons and nerves), rheumatologist (a type of immune system doctor), or a fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder) specialty center
C. You meet ONE of the following:
    1. You are a female AND 8 years of age or older
    2. You are a male AND 10 years of age or older
D. If you are a female of reproductive potential, you must have obtained a negative pregnancy test within 7 days prior to starting Sohonos

RENEWAL CRITERIA

Our guideline named **PALOVAROTENE (Sohonos)** requires the following rule(s) be met for renewal:

A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
B. You have experienced a positive clinical response to therapy

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PALTUSOTINE

Generic	Brand				
PALTUSOTINE HCL	PALSONIFY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PALTUSOTINE (Palsonify)** requires the following rule(s) be met for approval:
You have acromegaly (a type of hormone disorder)
You had an inadequate response (did not work) to surgery OR surgery is not an option for you
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)

RENEWAL CRITERIA

Our guideline named **PALTUSOTINE (Palsonify)** requires the following rule(s) be met for renewal:
You have acromegaly (a type of hormone disorder)
You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

Effective: 10/20/25

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PANITUMUMAB

Generic	Brand				
PANITUMUMAB	VECTIBIX				

GUIDELINES FOR USE

Our guideline named **PANITUMUMAB (Vectibix)** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your cancer is wild-type RAS (defined as wild-type in both KRAS and NRAS [types of genes without a specific mutation]), OR you have a KRAS G12C-mutation [type of abnormal change in a gene], as determined by a Food and Drug Administration (FDA)-approved test
D. **If your cancer is wild-type RAS, approval also requires ONE of the following:**
    1. Vectibix will be used in combination with FOLFOX (treatment regimen containing leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)
    2. Vectibix will be used as monotherapy (one drug treatment) AND you have disease progression (worsening) after treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy (drugs used to treat cancer)
E. **If your cancer has a KRAS G12C-mutation, approval also requires:**
    1. Vectibix will be used in combination with Lumakras (sotorasib)
    2. You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

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PARATHYROID HORMONE

Generic	Brand				
PARATHYROID HORMONE	NATPARA				

GUIDELINES FOR USE

Our guideline for **PARATHYROID HORMONE (Natpara)** requires the following rule(s) be met for approval:

You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)

Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

You have tried activated vitamin D (calcitriol) and calcium

Your hypoparathyroidism (low levels of a type of hormone) is NOT due to a calcium sensing receptor (CSR) mutation (an abnormal change in a type of gene)

Your hypoparathyroidism is NOT considered acute post-surgical hypoparathyroidism (low levels of a type of hormone due to surgery in the past 30 days)

Effective: 02/01/26

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PASIREOTIDE DIASPARTATE

Generic	Brand				
PASIREOTIDE DIASPARTATE	SIGNIFOR				

GUIDELINES FOR USE

Our guideline named **PASIREOTIDE DIASPARTATE (Signifor)** requires the following rule(s) be met for approval:
You have Cushing's disease (CD: a type of hormone disorder)
You are 18 years of age or older
You have undergone non-curative pituitary (a major hormone producing gland) surgery OR pituitary surgery is not an option
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
You have tried or have a contraindication to (harmful for you to use) ketoconazole

RENEWAL CRITERIA

Our guideline named **PASIREOTIDE DIASPARTATE (Signifor)** requires the following rule(s) be met for renewal:
You have Cushing's disease (CD: a type of hormone disorder)
You continue to have improvement of Cushing’s disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
You continue to tolerate treatment with Signifor

Effective: 02/01/26

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PASIREOTIDE PAMOATE

Generic	Brand				
PASIREOTIDE PAMOATE	SIGNIFOR LAR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PASIREOTIDE PAMOATE (Signifor LAR)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acromegaly (a type of hormone disorder)
- Cushing's disease (a type of hormone disorder)

If you have acromegaly, approval also requires:
- You had an inadequate response (did not work) to surgery, or surgery is not an option for you
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Sandostatin LAR Depot (octreotide acetate ER)

If you have Cushing's disease, approval also requires:
- You have undergone non-curative pituitary (a major hormone producing gland) surgery, or pituitary surgery is not an option for you
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- You have tried or have a contraindication to (harmful for you to use) oral ketoconazole

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PASIREOTIDE PAMOATE

RENEWAL CRITERIA

Our guideline named **PASIREOTIDE PAMOATE (Signifor LAR)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Acromegaly (a type of hormone disorder)
- Cushing's disease (a type of hormone disorder)

If you have acromegaly, renewal also requires:
- You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
- You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

If you have Cushing's disease, renewal also requires:
- You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
- You continue to tolerate Signifor LAR

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PATIROMER

Generic	Brand				
PATIROMER CALCIUM SORBITEX	VELTASSA				

GUIDELINES FOR USE

Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:

- You have hyperkalemia (high level of potassium in the blood)
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor) or cardiologist (a type of heart doctor)
- Veltassa is NOT being used as an emergency treatment for life-threatening hyperkalemia (high level of potassium in the blood)
- You are NOT currently receiving dialysis (process of removing excess water, toxins from the blood)
- You will NOT use Veltassa concurrently (at the same time) with another potassium binder (such as Lokelma [sodium zirconium cyclosilicate], sodium polystyrene sulfonate)
- You have tried ONE of the following to lower the risks for hyperkalemia (high level of potassium in the blood):
  - You are not taking both an angiotensin converting enzyme inhibitor (ACE-I, such as lisinopril, benazepril) and an angiotensin receptor blocker (ARB, such as valsartan, losartan) at the same time
  - You have lowered the dose of a renin-angiotensin-aldosterone system (RAAS) inhibitor (such as lisinopril, valsartan, spironolactone)
- You meet ONE of the following:
  - Your estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) is less than 30mL/min/1.73m(2), AND you have tried a loop diuretic (such as bumetanide, furosemide, torsemide)
  - Your estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) is at least 30 mL/min/1.73m(2), AND you have tried a loop diuretic (such as bumetanide, furosemide, torsemide) OR a thiazide diuretic (such as chlorthalidone, hydrochlorothiazide, metolazone)
- If you are 18 years of age or older, you have tried Lokelma (sodium zirconium cyclosilicate)

Effective: 10/01/25

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PATISIRAN (NSA)

Generic	Brand			
PATISIRAN SODIUM, LIPID COMPLEX	ONPATTRO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for approval:
You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
You will NOT use Onpattro concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Amvuttra [vutrisiran])
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Amvuttra (vutrisiran)
Your diagnosis is confirmed by ONE of the following:
- Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
- DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

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PATISIRAN (NSA)

RENEWAL CRITERIA

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for renewal:
You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
You will NOT use Onpattro concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Amvuttra [vutrisiran])

Effective: 07/01/24

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PAZOPANIB

Generic	Brand				
PAZOPANIB HCL	VOTRIENT, PAZOPANIB HCL				

GUIDELINES FOR USE

Our guideline named **PAZOPANIB (Votrient)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Advanced soft tissue sarcoma (STS: a type of cancer that starts in soft tissues [muscle, tendons, fat, lymph vessels, blood vessels, nerves])
- Advanced renal cell carcinoma (RCC: a type of kidney cancer)

If you have advanced soft tissue sarcoma, approval also requires:
- You are 18 years of age or older
- You have received prior chemotherapy (a type of cancer therapy such as doxorubicin, epirubicin)
- You do NOT have adipocytic soft tissue sarcoma (STS: a type of fat cell cancer) or gastrointestinal stromal tumors (GIST: a type of digestive tumor)

If you have advanced renal cell carcinoma, approval also requires:
- You are 18 years of age or older

Effective: 12/01/25

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PEANUT ALLERGEN POWDER-DNFP

Generic	Brand				
PEANUT ALLERGEN POWDER-DNFP	PALFORZIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:

A. You have an allergy to peanuts
B. You are 1 to 17 years of age
C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
D. You have a clinical history of an allergic reaction to peanuts
E. Palforzia will be used together with a peanut-avoidance diet
F. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
G. Your diagnosis is confirmed by ONE of the following:
    1. If you have completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR you have had a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
    2. If you have NOT completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR you have had a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

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PEANUT ALLERGEN POWDER-DNFP

RENEWAL CRITERIA

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:

A. You have an allergy to peanuts
B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
C. Palforzia will be used together with a peanut-avoidance diet
D. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
E. You meet ONE of the following:
    1. If you have completed a purposeful food challenge (a type of test): you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
    2. If you have NOT completed a purposeful food challenge (a type of test): you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

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PEGAPTANIB (NSA)

Generic	Brand			
PEGAPTANIB SODIUM	MACUGEN			

GUIDELINES FOR USE

Our guideline named **PEGAPTANIB (Macugen)** requires the following rule(s) be met for approval:
You have neovascular (wet) age-related macular degeneration (a chronic eye disorder that causes blurred vision or a blind spot in your visual field)
The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina specialist

Effective: 07/01/20

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PEGASPARGASE (NSA)

Generic	Brand				
PEGASPARGASE	ONCASPAR				

GUIDELINES FOR USE

Our guideline named **PEGASPARGASE (Oncaspar)** requires the following rule(s) be met for approval:
You have acute lymphoblastic leukemia (ALL: a type of blood cancer)
Oncaspar will be used as a part of a chemotherapeutic treatment plan with multiple drugs
You meet ONE of the following:
- Oncaspar will be used as a first-line therapy (drug used for initial treatment)
- You have a hypersensitivity to native forms of L-asparaginase (you are allergic to natural forms of a type of enzyme/protein)

Effective: 04/15/24

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PEGCETACOPLAN - INTRAOCULAR

Generic	Brand				
PEGCETACOPLAN	SYFOVRE				

GUIDELINES FOR USE

Our guideline named **PEGCETACOPLAN - INTRAOCULAR (Syfovre)** requires the following rule(s) be met for approval:
You have geographic atrophy (GA: an advanced type of eye disease) due to age-related macular degeneration (AMD: a type of eye disease)

Effective: 02/01/26

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PEGCETACOPLAN - SQ

Generic	Brand				
PEGCETACOPLAN	EMPAVELI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Complement 3 glomerulopathy (C3G: a type of kidney disease) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN: a type of kidney disease)

If you have paroxysmal nocturnal hemoglobinuria, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
- You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

If you have complement 3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis, approval also requires:

- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
- Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
- You have a urine-protein creatine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1g/g
- You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30mL/min/1.73m(2)
- You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
- You will NOT use Empaveli concurrently (at the same time) with another complement inhibitor (such as Fabhalta [iptacopan]) for the same indication

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PEGCETACOPLAN - SQ

RENEWAL CRITERIA

Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Complement 3 glomerulopathy (C3G: a type of kidney disease) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN: a type of kidney disease)

If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:

- You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (baseline is defined as your condition after treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
- You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

If you have complement 3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis, renewal also requires:

- You have had a reduction (decrease) in proteinuria (high levels of protein in the urine) OR you have improved or stable kidney function compared to baseline (before treatment)
- You will NOT use Empaveli concurrently (at the same time) with another complement inhibitor (such as Fabhalta [iptacopan]) for the same indication

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PEGFILGRASTIM

Generic	Brand				
PEGFILGRASTIM	NEULASTA, NEULASTA ONPRO				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM (Neulasta, Neulasta Onpro)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. **If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You meet ONE of the following:
      a. You are requesting Neulasta AND you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)
      b. You are requesting Neulasta Onpro AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Udenyca Onbody (pegfilgrastim-cbqv)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You meet ONE of the following:
      a. You are requesting Neulasta AND you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)
      b. You are requesting Neulasta Onpro AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Udenyca Onbody (pegfilgrastim-cbqv)

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PEGFILGRASTIM-APGF

Generic	Brand				
PEGFILGRASTIM-APGF	NYVEPRIA				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM-APGF (Nyvepria)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. **If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

Effective: 08/01/26

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PEGFILGRASTIM-BMEZ

Generic	Brand				
PEGFILGRASTIM-BMEZ	ZIEXTENZO				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM-BMEZ (Ziextenzo)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. **If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

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PEGFILGRASTIM-CBQV

Generic	Brand				
PEGFILGRASTIM-CBQV	UDENYCA, UDENYCA ONBODY				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM - CBQV (Udenyca, Udenyca Onbody)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. **If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. If you are requesting Udenyca, approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. If you are requesting Udenyca, approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

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PEGFILGRASTIM-FPGK

Generic	Brand				
PEGFILGRASTIM-FPGK	STIMUFEND				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM-FPGK (Stimufend)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. **If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

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PEGFILGRASTIM-JMDB

Generic	Brand				
PEGFILGRASTIM-JMDB	FULPHILA				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM-JMDB (Fulphila)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. **If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

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PEGFILGRASTIM-PBBK

Generic	Brand				
PEGFILGRASTIM-PBBK	FYLNETRA				

GUIDELINES FOR USE

Our guideline named **PEGFILGRASTIM-PBBK (Fylnetra)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. **If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

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PEGINTERFERON ALFA 2A OR 2B

Generic	Brand				
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK				
PEGINTERFERON ALFA-2B	PEGINTRON				

GUIDELINES FOR USE

Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys, PegIntron)** requires the following rule(s) be met for approval:
You have chronic hepatitis B (a type of liver infection)
Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive condition), infectious disease specialist (a doctor who specializes in the treatment of infections), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

If you are 3 to 17 years of age, approval also requires:
- You do NOT have cirrhosis (liver damage)
- Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive chronic hepatitis B
- You have evidence of viral replication (virus is multiplying in the body) with elevated serum alanine aminotransferase (ALT: a type of liver enzyme test)

If you are 18 years of age or older, approval also requires:
- Your blood test shows you have HBeAg (marker of active virus multiplying in the body)-positive or HBeAg-negative chronic hepatitis B
- You have compensated liver disease (a type of liver condition) with evidence of viral replication and liver inflammation

Note: Pegasys and PegIntron will not be approved for the treatment of hepatitis C.

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PEG-INTERFERON ALFA-2B

Generic	Brand				
PEGINTERFERON ALFA-2B	SYLATRON				

GUIDELINES FOR USE

Our guideline named **PEG-INTERFERON ALFA-2B (Sylatron)** requires the following rule(s) be met for approval:
You meet ONE of the following:
- You are currently taking Sylatron and have NOT received 5 years of treatment with Sylatron
- You have melanoma (skin cancer) with microscopic or gross nodal involvement (presence of cancer cells in the lymph nodes) within 84 days of definitive surgical resection (removal)

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PEGLOTICASE

Generic	Brand				
PEGLOTICASE	KRYSTEXXA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGLOTICASE (Krystexxa)** requires the following rules be met for approval:
You have chronic gout (a type of long-term joint condition)
You are 18 years of age or older
Your disease is refractory (did not respond) to conventional (standard) therapy
You had a baseline serum uric acid level (a type of lab test) of at least 8 mg/dL while on conventional (standard) gout medications (such as allopurinol)
You do not have glucose-6-phosphate dehydrogenase (G6PD) deficiency (a genetic disorder that affects red blood cells)
You will NOT use Krystexxa concurrently (at the same time) with other urate-lowering therapy (such as xanthine oxidase inhibitors, febuxostat, probenecid)
You have tried or have a contraindication to (harmful for you to use) TWO conventional (standard) gout medications (such as allopurinol, probenecid) at a maximum tolerated dose for at least 3 months
Krystexxa will be given with weekly oral methotrexate 15mg and folic acid, unless contraindicated (harmful for you to use)
You have symptomatic gout as shown by ONE of the following:
- At least 3 or more gout flares (episodes of pain or swelling associated with a type of joint condition) in the previous 18 months
- History of at least 1 gout tophus (uric acid crystallizes in joints like hands/feet)
- Gouty arthritis (severe pain and inflammation in joints due to gout)

RENEWAL CRITERIA

Our guideline named **PEGLOTICASE (Krystexxa)** requires a sustained serum uric level (a type of lab test) below 6 mg/dL for renewal.

Effective: 10/13/25

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PEGUNIGALSIDASE ALFA-IWXJ (NSA)

Generic	Brand				
PEGUNIGALSIDASE ALFA-IWXJ	ELFABRIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGUNIGALSIDASE ALFA-IWXJ (Elfabrio)** requires the following rule(s) be met for approval:
You have Fabry disease (a rare genetic disease)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor), cardiologist (a type of heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
You are symptomatic OR have evidence of injury to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury may include decreased glomerular filtration rate (GFR: a tool for evaluating kidney function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (magnetic resonance imaging: type of imaging lab), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
You will NOT use Elfabrio concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Galafold [migalastat])
If you are a female, approval also requires:
You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing
If you are a male, approval also requires ONE of the following:
You do NOT have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing

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PEGUNIGALSIDASE ALFA-IWXJ (NSA)

RENEWAL CRITERIA

Our guideline named **PEGUNIGALSIDASE ALFA-IWXJ (Elfabrio)** requires the following rule(s) be met for renewal:

You have Fabry disease (a rare genetic disease)

You will NOT use Elfabrio concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Galafold [migalastat])

You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:

- Symptoms (such as pain, hypohidrosis [less sweating]/anhidrosis [no sweating], exercise intolerance, GI [gastrointestinal] symptoms, angiokeratomas [dark red-blue raised spots on the skin], abnormal cornea [a part of the eye], tinnitus [ringing in the ears]/hearing loss)
- Imaging such as brain/cardiac MRI [magnetic resonance imaging: type of imaging lab], DEXA [a type of bone scan], renal [kidney] ultrasound)
- Laboratory or histological (viewed by microscope) testing (such as GL-3 [globotriaosylceramide: a type of fat] in plasma/urine, renal biopsy [removal of cells or tissue from the body for examination])

Effective: 01/01/25

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PEGVALIASE-PQPZ

Generic	Brand				
PEGVALIASE-PQPZ	PALYNZIQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rule(s) be met for approval:
You have phenylketonuria (PKU: a type of genetic metabolic disorder)
You are 12 years of age or older
Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist (a doctor that treats metabolic or gene disorders)
You follow a phenylalanine-restricted diet (a type of diet)
You have uncontrolled blood phenylalanine (Phe) levels greater than 600 micromoles/L on your existing management, as confirmed by a measurement in the last 30 days
You will NOT use Palynziq concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Sephience [sepiapterin])

RENEWAL CRITERIA

Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rule(s) be met for renewal:
You have phenylketonuria (PKU: a type of genetic metabolic disorder)
Your phenylalanine (Phe) levels have decreased by at least 20% compared to baseline (before treatment) or to a level below 600 micromoles/L
You will NOT use Palynziq concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Sephience [sepiapterin])

Effective: 03/11/26

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PEGVISOMANT

Generic	Brand				
PEGVISOMANT	SOMAVERT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGVISOMANT (Somavert)** requires the following rule(s) be met for approval:

A. You have acromegaly (a type of hormone disorder)
B. You had an inadequate response (did not work) to surgery or radiation, OR surgery or radiation is not an option for you
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
E. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)
    2. You will use Somavert concurrently (at the same time) with a somatostatin analog (a type of medication such as Mycapssa, Sandostatin LAR Depot [octreotide acetate ER])

RENEWAL CRITERIA

Our guideline named **PEGVISOMANT (Somavert)** requires the following rule(s) be met for renewal:

A. You have acromegaly (a type of hormone disorder)
B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
C. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

Effective: 07/01/26

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PEGZILARGINASE-NBLN

Generic	Brand				
PEGZILARGINASE-NBLN	LOARGYS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGZILARGINASE-NBLN (Loargys)** requires the following rule(s) be met for approval:

A. You have Arginase 1 Deficiency (ARG1-D: a rare metabolic disorder)
B. You are 2 years of age or older
C. Loargys will be used together with dietary protein restriction
D. Therapy is prescribed by or in consultation with a metabolic specialist
E. You have a documented plasma arginine level (a type of lab test) of at least 250 micromole/liter

RENEWAL CRITERIA

Our guideline named **PEGZILARGINASE-NBLN (Loargys)** requires the following rule(s) be met for renewal:

A. You have Arginase 1 Deficiency (ARG1-D: a rare metabolic disorder)
B. You have shown improvement of symptoms or reduction (decrease) of arginine levels (a type of lab test)

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PEMBROLIZUMAB

Generic	Brand				
PEMBROLIZUMAB	KEYTRUDA				

GUIDELINES FOR USE

Our guideline named **PEMBROLIZUMAB (Keytruda)** requires the following rule(s) be met for approval:

A. You have ONE of the following:

1. Unresectable or metastatic melanoma (type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
2. Stage IIB, IIC, or III melanoma (type of skin cancer)
3. Non-small cell lung cancer (type of lung cancer)
4. Unresectable advanced or metastatic malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery or has spread to other parts of the body)
5. Head and neck squamous cell carcinoma (type of neck cancer)
6. Classical Hodgkin lymphoma (type of immune system cancer)
7. Primary mediastinal large B-cell lymphoma (type of immune system cancer)
8. Locally advanced or metastatic urothelial carcinoma (type of urinary system cancer that has spread to other parts of the body)
9. Bladder cancer
10. Unresectable or metastatic solid tumor (type of cancer that cannot be removed by surgery or has spread to other parts of the body)
11. Unresectable or metastatic colorectal cancer (CRC: type of colon or rectal cancer that cannot be removed by surgery or has spread to other parts of the body)
12. Locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue or has spread to other parts of the body)
13. Locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with an epicenter of 1 to 5 centimeters above the GEJ) carcinoma (a type of digestive system cancer that has spread to nearby tissue or to other parts of the body)
14. Cervical cancer
15. Hepatocellular carcinoma (liver cancer)
16. Locally advanced unresectable or metastatic biliary tract cancer (BTC) (type of bile duct cancer that cannot be removed with surgery or has spread to other parts of the body)

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

17. Recurrent locally advanced or metastatic Merkel cell carcinoma (MCC: type of skin cancer that has returned or has spread to other parts of the body)
18. Renal cell carcinoma (kidney cancer)
19. Endometrial carcinoma (type of cancer that starts in the uterus)
20. Recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned, or has spread to other parts of the body or to nearby tissue or lymph nodes)
21. High-risk early-stage triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors)
22. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
23. Locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)
24. Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (types of reproductive system or abdomen cancers)

B. **If you have unresectable or metastatic melanoma, approval also requires:**

1. You will NOT use Keytruda concurrently (at the same time) with a targeted therapy (BRAF inhibitors [such as Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [such as Mekinist (trametinib)], and NTRK inhibitors [such as Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

C. **If you have Stage IIB, IIC, or III melanoma, approval also requires:**

1. You are 12 years of age or older
2. You have undergone complete resection (completely removed by surgery)
3. Keytruda will be used as adjuvant (add-on) treatment

D. **If you have metastatic nonsquamous non-small cell lung cancer, approval also requires:**

1. Keytruda will be used in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)
2. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)

E. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**

1. Keytruda will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

F. **If you have non-small cell lung cancer, approval also requires:**
1. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
2. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
3. You meet ONE of the following:
    a. You have stage III non-small cell lung cancer AND you are not a candidate for surgical resection (removal) or definitive chemoradiation (a type of treatment)
    b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

G. **If you have metastatic non-small cell lung cancer, approval also requires:**
1. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
2. You experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
3. You meet ONE of the following:
    a. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
    b. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
    c. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

H. **If you have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer, approval also requires:**
1. Keytruda will be used in combination with platinum-containing chemotherapy (such as cisplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent (not given in combination with chemotherapy) as adjuvant (add-on) treatment after surgery following prior use in combination with platinum-containing chemotherapy

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

I. **If you have Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer, approval also requires:**

1. You are 18 years of age or older
2. Keytruda will be used as adjuvant (add-on) treatment following resection (removed by surgery) and platinum-based chemotherapy (such as cisplatin, carboplatin)

J. **If you have unresectable advanced or metastatic malignant pleural mesothelioma, approval also requires:**

1. You are 18 years of age or older
2. Keytruda will be given in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)

K. **If you have head and neck squamous cell carcinoma, approval also requires ONE of the following:**

1. Your cancer is resectable (able to be removed by surgery) and locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) and you meet ALL of the following:
   a. You are 18 years of age or older
   b. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   c. Keytruda will be used as single-agent neoadjuvant treatment (given before main treatment) and then continued as adjuvant (add-on) treatment in combination with radiotherapy (RT: a type of cancer treatment), OR Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT
2. Your cancer is either metastatic (has spread to other parts of the body) or both unresectable (unable to remove by surgery) and recurrent (has returned), and you meet ONE of the following:
   a. Keytruda will be given in combination with platinum and fluorouracil (FU)
   b. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. Your cancer is recurrent (has returned) or metastatic (has spread to other parts of the body); AND you experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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GUIDELINES FOR USE (CONTINUED)

L. **If you have classical Hodgkin lymphoma, approval also requires ONE of the following:**
1. You are 18 years of age or older AND have relapsed (disease has returned) or refractory (disease is resistant to treatment) classical Hodgkin lymphoma
2. You have refractory (disease is resistant to treatment) classical Hodgkin lymphoma or classical Hodgkin lymphoma that has relapsed (disease has returned) after 2 or more prior lines of therapy

M. **If you have primary mediastinal large B-cell lymphoma, approval also requires ONE of the following:**
1. You have refractory primary mediastinal large B-cell lymphoma (type of immune system cancer that is resistant to treatment)
2. You have relapsed (disease has returned) after 2 or more prior lines of therapy

N. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
1. Keytruda will be used in combination with enfortumab vedotin (Padcev), AND you are 18 years of age or older
2. You are not eligible for any platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
3. You have disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
4. You have disease progression (worsening) within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

O. **If you have bladder cancer, approval also requires ONE of the following:**
1. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall); AND you are 18 years of age or older; AND Keytruda will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment (given before main treatment), and then continued as adjuvant (add-on) treatment after a cystectomy (surgery to remove part or all of the urinary bladder)
2. You have Bacillus Calmette-Guerin (BCG: a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a type of early-stage bladder cancer); AND you are not eligible for or have chosen not to undergo a cystectomy (surgery to remove part or all of the urinary bladder)

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GUIDELINES FOR USE (CONTINUED)

P. **If you have an unresectable or metastatic solid tumor, approval also requires:**
1. You meet ONE of the following:
   a. Your tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test
   b. Your tumor is tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food and Drug Administration (FDA)-approved test
2. Your disease has progressed (worsened) following prior treatment, and you have no alternative treatment options

Q. **If you have unresectable or metastatic colorectal cancer, approval also requires:**
1. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by an FDA-approved test

R. **If you have locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   3. You meet ONE of the following:
   a. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-POSITIVE, and Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
   b. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-NEGATIVE, and Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

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GUIDELINES FOR USE (CONTINUED)

S. **If you have locally advanced or metastatic esophageal or gastroesophageal junction carcinoma, approval also requires:**

1. Your tumor is not amenable (responsive) to surgical resection (removal) or definitive chemoradiation (a type of treatment)
2. You meet ONE of the following:
   a. Keytruda will be used in combination with platinum- and fluoropyrimidine-based chemotherapy; AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1)
   b. Keytruda will be used after one or more prior lines of systemic therapy; AND you have a tumor of squamous cell histology (cancer from flat surface-lining cells) that expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

T. **If you have cervical cancer, approval also requires ONE of the following:**

1. Your cancer is locally advanced, your cancer is FIGO 2014 Stage III-IVA (a way to classify the size and spread of the cancer) and involves the lower third of the vagina, hydronephrosis (swelling of kidney)/a non-functioning kidney, or has spread to adjacent (nearby) pelvic organs; AND Keytruda will be used in combination with chemoradiotherapy (CRT: a type of therapy to treat cancer)
2. You have persistent, recurrent, or metastatic cancer (cancer that does not go away, has returned, or has spread to other parts of the body); AND Keytruda will be used in combination with chemotherapy (such as paclitaxel, cisplatin, carboplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. You have recurrent or metastatic cancer (cancer that has returned or has spread to other parts of the body); AND you have experienced disease progression (worsening) on or after chemotherapy; AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test

U. **If you have hepatocellular carcinoma, approval also requires:**

1. Your cancer is caused by hepatitis B (a type of liver infection)
2. You have received prior systemic therapy (such as Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (such as Opdivo [nivolumab])

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GUIDELINES FOR USE (CONTINUED)

V. **If you have locally advanced unresectable or metastatic biliary tract cancer, approval also requires:**
1. Keytruda will be used in combination with gemcitabine and cisplatin

W. **If you have renal cell carcinoma, approval also requires ONE of the following:**
1. You have advanced renal cell carcinoma; you are 18 years of age or older; AND Keytruda will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)
2. Keytruda will be used as adjuvant (add-on) treatment; AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
3. You are 18 years of age or older; AND Keytruda will be used in combination with Welireg (belzutifan), Keytruda will be used as adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer), AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)

X. **If you have primary advanced or recurrent endometrial carcinoma, approval also requires:**
1. Keytruda will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

Y. **If you have advanced endometrial carcinoma, approval also requires:**
1. You have experienced disease progression (worsening) following prior systemic therapy (treatment that affects the entire body)
2. You are not a candidate for curative surgery or radiation
3. You meet ONE of the following:
   a. You will use Keytruda in combination with lenvatinib (Lenvima), AND your cancer is mismatch repair proficient (pMMR) as determined by a Food and Drug Administration (FDA)-approved test OR is NOT microsatellite instability-high (MSI-H) (characteristics that help determine the type of cancer and what treatment options there are for it)
   b. Your cancer is microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test

Z. **If you have recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma, approval also requires:**
   1. Your disease is not curable by surgery or radiation

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

AA. **If you have high-risk early-stage triple-negative breast cancer, approval also requires:**

1. Keytruda will be used in combination with chemotherapy (such as carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant (add-on) treatment after surgery following prior use in combination with chemotherapy

BB. **If you have unresectable locally advanced or metastatic triple-negative breast cancer, approval also requires:**

1. Keytruda will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
2. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-authorized test

CC. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer, approval also requires:**

1. Keytruda will be used in combination with chemotherapy (such as paclitaxel, gemcitabine, carboplatin)
2. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

DD. **If you have epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, approval also requires:**

1. You are 18 years of age or older
2. You have platinum-resistant cancer (cancer that no longer responds to a type of treatment)
3. Keytruda will be used in combination with paclitaxel
4. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
5. You have received one or more prior systemic treatment regimens (treatment that affects the entire body)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

Generic	Brand				
PEMBROLIZUM-BERAHYALURON-PMPH	KEYTRUDA QLEX				

GUIDELINES FOR USE

Our guideline named **PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH (Keytruda Qlex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   2. Stage IIB, IIC, or III melanoma (type of skin cancer)
   3. Non-small cell lung cancer (type of lung cancer)
   4. Unresectable advanced or metastatic malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery or has spread to other parts of the body)
   5. Head and neck squamous cell carcinoma (type of neck cancer)
   6. Locally advanced or metastatic urothelial carcinoma (type of urinary system cancer that has spread to other parts of the body)
   7. Bladder cancer
   8. Unresectable or metastatic solid tumor (type of cancer that cannot be removed by surgery or has spread to other parts of the body)
   9. Unresectable or metastatic colorectal cancer (CRC: type of colon or rectal cancer that cannot be removed by surgery or has spread to other parts of the body)
   10. Locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue or has spread to other parts of the body)
   11. Locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with an epicenter of 1 to 5 centimeters above the GEJ) carcinoma (a type of digestive system cancer that has spread to nearby tissue or to other parts of the body)
   12. Cervical cancer
   13. Hepatocellular carcinoma (liver cancer)
   14. Locally advanced unresectable or metastatic biliary tract cancer (BTC) (type of bile duct cancer that cannot be removed with surgery or has spread to other parts of the body)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

15. Recurrent locally advanced or metastatic Merkel cell carcinoma (MCC: type of skin cancer that has returned or has spread to other parts of the body)
16. Renal cell carcinoma (kidney cancer)
17. Endometrial carcinoma (type of cancer that starts in the uterus)
18. Recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned, or has spread to other parts of the body or to nearby tissue or lymph nodes)
19. High-risk early-stage triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors)
20. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
21. Locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)
22. Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (types of reproductive system or abdomen cancers)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You are 18 years of age or older
C. **If you have Stage IIB, IIC, or III melanoma, approval also requires:**
   1. You are 12 years of age or older
   2. You have undergone complete resection (completely removed by surgery)
   3. Keytruda Qlex will be used as adjuvant (add-on) treatment
D. **If you have metastatic nonsquamous non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)
   3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
E. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

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GUIDELINES FOR USE (CONTINUED)

F. **If you have non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
   3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
   4. You meet ONE of the following:
      a. You have stage III non-small cell lung cancer AND you are not a candidate for surgical resection (removal) or definitive chemoradiation (a type of treatment)
      b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

G. **If you have metastatic non-small cell lung cancer, approval also requires:**
   4. You are 18 years of age or older
   5. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
   6. You experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   7. You meet ONE of the following:
      d. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
      e. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
      f. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

H. **If you have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with platinum-containing chemotherapy (such as cisplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent (not given in combination with chemotherapy) as adjuvant (add-on) treatment after surgery following prior use in combination with platinum-containing chemotherapy

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

I. **If you have Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used as adjuvant (add-on) treatment following resection (removed by surgery) and platinum-based chemotherapy (such as cisplatin, carboplatin)

J. **If you have unresectable advanced or metastatic malignant pleural mesothelioma, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be given in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)

K. **If you have head and neck squamous cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is resectable (able to be removed by surgery) and locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) and you meet ALL of the following:
         i. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
         ii. Keytruda Qlex will be used as single-agent neoadjuvant treatment (given before main treatment) and then continued as adjuvant (add-on) treatment in combination with radiotherapy (RT: a type of cancer treatment), OR Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT
      b. Your cancer is either metastatic (has spread to other parts of the body) or both unresectable (unable to remove by surgery) and recurrent (has returned), and you meet ONE of the following:
         i. Keytruda Qlex will be used in combination with platinum and fluorouracil (FU)
         ii. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
      c. Your cancer is recurrent (has returned) or metastatic (has spread to other parts of the body); AND you experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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GUIDELINES FOR USE (CONTINUED)

L. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev)
      b. You are not eligible for any platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
      c. You have disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
      d. You have disease progression (worsening) within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

M. **If you have bladder cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall); AND Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment (given before main treatment), and then continued as adjuvant (add-on) treatment after a cystectomy (surgery to remove part or all of the urinary bladder)
      b. You have Bacillus Calmette-Guerin (BCG: a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a type of early-stage bladder cancer); AND you are not eligible for or have chosen not to undergo a cystectomy (surgery to remove part or all of the urinary bladder)

N. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 12 years of age or older
   2. You meet ONE of the following:
      a. Your tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test
      b. Your tumor is tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food and Drug Administration (FDA)-approved test
   3. Your disease has progressed (worsened) following prior treatment, and you have no alternative treatment options

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GUIDELINES FOR USE (CONTINUED)

O. **If you have unresectable or metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by a Food and Drug Administration (FDA)-approved test

P. **If you have locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   3. You meet ONE of the following:
      a. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-POSITIVE, and Keytruda Qlex will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
      b. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-NEGATIVE, and Keytruda Qlex will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

Q. **If you have locally advanced or metastatic esophageal or gastroesophageal junction carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor is not amenable (responsive) to surgical resection (removal) or definitive chemoradiation (a type of treatment)
   3. You meet ONE of the following:
      a. Keytruda Qlex will be used in combination with platinum- and fluoropyrimidine-based chemotherapy; AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-authorized test
      b. Keytruda Qlex will be used after one or more prior lines of systemic therapy; AND you have a tumor of squamous cell histology (cancer from flat surface-lining cells) that expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-authorized test

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

R. **If you have cervical cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have locally advanced cancer (cancer that has spread from where it started to nearby tissue or lymph nodes); AND Keytruda Qlex will be used in combination with chemoradiotherapy (CRT: a type of therapy to treat cancer); AND your cancer involves the lower third of the vagina, hydronephrosis (swelling of kidney)/a non-functioning kidney, or has spread to adjacent (nearby) pelvic organs (FIGO 2014 Stage III-IVA: a way to classify the size and spread of the cancer)
      b. You have persistent, recurrent, or metastatic cancer (cancer that does not go away, has returned, or has spread to other parts of the body); AND Keytruda Qlex will be used in combination with chemotherapy (such as paclitaxel, cisplatin, carboplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
      c. You have recurrent (has returned) or metastatic (has spread to other parts of the body) cancer; AND you have experienced disease progression (worsening) on or after chemotherapy; AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test

S. **If you have hepatocellular carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is caused by hepatitis B (a type of liver infection)
   3. You have received prior systemic therapy (such as Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (such as Opdivo [nivolumab])

T. **If you have locally advanced unresectable or metastatic biliary tract cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with gemcitabine and cisplatin

U. **If you have recurrent locally advanced or metastatic Merkel cell carcinoma, approval also requires:**
   1. You are 12 years of age or older

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GUIDELINES FOR USE (CONTINUED)

V. **If you have renal cell carcinoma, approval also requires ONE of the following:**
   1. You have advanced renal cell carcinoma; you are 18 years of age or older; AND Keytruda Qlex will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)
   2. You are 18 years of age or older; Keytruda Qlex will be used as adjuvant (add-on) treatment; AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
   3. You are 18 years of age or older; AND Keytruda Qlex will be used in combination with Welireg (belzutifan), Keytruda Qlex will be used as adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer), AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)

W. **If you have primary advanced or recurrent endometrial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

X. **If you have advanced endometrial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have experienced disease progression (worsening) following prior systemic therapy (treatment that affects the entire body)
   3. You are not a candidate for curative surgery or radiation
   4. You meet ONE of the following:
      a. You will use Keytruda Qlex in combination with lenvatinib (Lenvima), AND your cancer is mismatch repair proficient (pMMR) OR not microsatellite instability-high (MSI-H) (characteristics that help determine the type of cancer and what treatment options there are for it) as determined by a Food and Drug Administration (FDA)-approved test
      b. Your cancer is microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by a Food and Drug Administration (FDA)-approved test

Y. **If you have recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your disease is not curable by surgery or radiation

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GUIDELINES FOR USE (CONTINUED)

Z. **If you have high-risk early-stage triple-negative breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with chemotherapy (such as carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant (add-on) treatment after surgery following prior use in combination with chemotherapy

AA. **If you have unresectable locally advanced or metastatic triple-negative breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
   3. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10), as determined by a Food and Drug (FDA)-authorized test

BB. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Keytruda Qlex will be used in combination with chemotherapy (such as paclitaxel, gemcitabine, carboplatin)
   3. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

CC. **If you have epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have platinum-resistant cancer (cancer that no longer responds to a type of treatment)
   3. Keytruda Qlex will be used in combination with paclitaxel
   4. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   5. You have received one or more prior systemic treatment regimens (treatment that affects the entire body)

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PEMETREXED (NSA)

Generic	Brand				
PEMETREXED DISODIUM	ALIMTA, PEMETREXED DISODIUM, PEMRYDI RTU				
PEMETREXED	PEMFEXY, PEMETREXED				

GUIDELINES FOR USE

Our guideline named **PEMETREXED (Alimta, Pemfexy, Pemrydi RTU)** requires the following rule(s) be met for approval:

The request is for ONE of the following:

- Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to nearby tissue or lymph nodes or other parts of the body)
- Metastatic, non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
- Recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has returned and spread to other parts of the body)
- Locally advanced or metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or other parts of the body)
- Malignant pleural mesothelioma (a type of cancer)
- The requested medication is being used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:

- The requested medication will be used in combination with cisplatin
- The requested medication will be used as a single agent, maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)

If you have metastatic, non-squamous, non-small cell lung cancer, approval also requires:

- The requested medication will be used in combination with pembrolizumab and platinum chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)
- You do NOT have EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations (types of gene mutations)

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PEMETREXED (NSA)

GUIDELINES FOR USE (CONTINUED)

If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:
- The requested medication will be used as a single agent
- You have received prior chemotherapy

If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following criteria:
  - The requested medication will be used in combination with Tagrisso (osimertinib) and platinum-based chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)
  - The requested medication will be used in combination with Rybrevant (amivantamab-vmjw) and carboplatin

If you have malignant pleural mesothelioma, approval also requires:
- The requested medication will be used in combination with cisplatin
- Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

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PEMETREXED DIPOTASSIUM

Generic	Brand				
PEMETREXED DIPOTASSIUM	AXTLE, PEMETREXED DIPOTASSIUM				

GUIDELINES FOR USE

Our guideline named **PEMETREXED DIPOTASSIUM (Axtle)** requires the following rule(s) be met for approval:

The request is for ONE of the following:

- Non-squamous non-small cell lung cancer (NSCLC) (a type of lung cancer)
- Malignant pleural mesothelioma (a type of cancer)
- The requested medication will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have non-squamous, non-small cell lung cancer, approval also requires ONE of the following:

- Your cancer is metastatic (has spread to other parts of the body), the requested medication will be used in combination with Keytruda (pembrolizumab) and platinum chemotherapy (such as cisplatin, carboplatin), AND you do NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor aberrations (types of gene mutations)
- Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), AND the requested medication will be used in combination with cisplatin
- Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), the requested medication will be used as a single agent, AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)
- Your cancer is recurrent (has returned) and metastatic (has spread to other parts of the body), AND you have received prior chemotherapy (medication used to treat cancer)

If you have malignant pleural mesothelioma, approval also requires:

- The requested medication will be used in combination with cisplatin
- Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative (to cure) surgery

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PEMETREXED DITROMETHAMINE (NSA)

Generic	Brand				
PEMETREXED DITROMETHAMINE	PEMETREXED DITROMETHAMINE				

GUIDELINES FOR USE

Our guideline named **PEMETREXED DITROMETHAMINE** requires the following rule(s) be met for approval:

The request is for ONE of the following:

- Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue/lymph nodes or other part of the body)
- Recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
- Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or other parts of the body)
- Malignant pleural mesothelioma (a type of cancer)
- The requested medication is being used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:

- The requested medication will be used in combination with cisplatin
- The requested medication will be used as a single agent, maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy (e.g., cisplatin, carboplatin)

If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:

- The requested medication will be used as a single agent
- You have received prior chemotherapy

If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:

- You are 18 years of age or older
- You meet ONE of the following criteria:
  - The requested medication will be used in combination with Tagrisso (osimertinib) and platinum-based chemotherapy (such as cisplatin, carboplatin)
  - The requested medication will be used in combination with Rybrevant (amivantamab-vmjw) and carboplatin

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PEMETREXED DITROMETHAMINE (NSA)

GUIDELINES FOR USE (CONTINUED)

If you have malignant pleural mesothelioma, approval also requires:

The requested medication will be used in combination with cisplatin

Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

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PEMIGATINIB

Generic	Brand				
PEMIGATINIB	PEMAZYRE				

GUIDELINES FOR USE

Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:
You have ONE of the following:

1. Unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread to nearby tissue and lymph nodes and cannot be removed by surgery, or it has spread to other parts of the body)
2. Relapsed or refractory myeloid/lymphoid neoplasms (a type of blood cancer that has returned or did not respond to treatment)

If you have unresectable locally advanced or metastatic cholangiocarcinoma, approval also requires:

1. You are 18 years of age or older
2. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
3. You have a fibroblast growth factor receptor 2 (FGFR2: a type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test
4. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

If you have relapsed or refractory myeloid/lymphoid neoplasms, approval also requires:

1. You are 18 years of age or older
2. You have a fibroblast growth factor receptor 1 (FGFR1: a type of protein) rearrangement
3. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

Effective: 02/01/26

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PEMIVIBART (NSA)

Generic	Brand				
PEMIVIBART	PEMGARDA (EUA)				

GUIDELINES FOR USE

Our guideline named **PEMIVIBART (Pemgarda)** requires the following rule(s) be met for approval:

The request is for pre-exposure prophylaxis (to prevent infection) of coronavirus disease 2019 (COVID-19: a type of viral infection)

You are 12 years of age or older

You weigh at least 40 kilograms (88 pounds)

You are NOT currently infected with the SARS-CoV-2 virus (a type of virus that causes COVID-19 illness)

You have NOT been recently exposed to (come in contact with) an individual infected with the SARS-CoV-2 virus

You are moderately-to-severely immunocompromised (low immune system) due to a medical condition (such as HIV [human immunodeficiency virus: an immune system disease caused by a virus], primary immunodeficiency disease [genetic disease where the immune system is weak], acute leukemia [a type of blood cancer]) OR immunosuppressive medication or treatment (such as sirolimus, mycophenolate, chemotherapy [a type of cancer treatment])

You are unlikely to have an adequate immune response to the COVID-19 vaccination (vaccine may not work effectively for you)

Effective: 10/12/24

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PENICILLAMINE

Generic	Brand				
PENICILLAMINE	CUPRIMINE, PENICILLAMINE				
PENICILLAMINE	DEPEN, PENICILLAMINE				
PENICILLAMINE	D-PENAMINE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Wilson's disease (a type of genetic disorder)
   2. Cystinuria (a type of genetic disorder)
   3. Severe, active rheumatoid arthritis (a type of joint condition)

B. I**f you have Wilson's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
   2. The requested medication will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
   3. You meet ONE of the following:
      a. You have genetic testing confirming an ATP7B mutation (an abnormal change in a type of gene)
      b. You meet ONE of the following:
         i. You have a 24-hour urinary copper excretion (a type of lab test) (greater than 40 micrograms/24 hours)
         ii. You have a liver biopsy (removal of cells or tissue from the liver for examination) with copper dry weight greater than 75 micrograms/gram
         iii. You have a serum ceruloplasmin (a type of lab test) level less than 20mg/dL
   4. If you are requesting Cuprimine, you have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine (Depen, D-Penamine)

(Initial criteria continued on next page)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you have cystinuria, approval also requires:**
   1. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor) or urologist (a type of doctor who treats conditions affecting the organs in the body that make and remove urine)
   2. You have failed to respond to an adequate trial of or have a contraindication to (harmful for you to use) conservative therapy which includes ALL of the following:
      a. Increased fluid intake
      b. Reductions in sodium and protein intake
      c. Urinary alkalinization (a process that makes urine basic)
   3. You have nephrolithiasis (kidney stones) and meet ONE of the following:
      a. Your kidney stone analysis shows that there is a presence of cystine (an amino acid)
      b. Your urine analysis shows that there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      c. You have a family history of cystinuria (a type of genetic disorder) AND tested positive for the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body)
   4. If you are requesting Depen (penicillamine tablets) or D-Penamine, you have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine capsules (Cuprimine)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   2. You do not have a history or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine (Depen, D-Penamine)

E. **If you have an active prior authorization approval for Depen, D-Penamine** will be approved without meeting additional criteria during the period of Depen shortage.

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PENICILLAMINE

RENEWAL CRITERIA

NOTE: For the diagnosis of Wilson's disease, please refer to the Initial Criteria section.

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Cystinuria (a type of genetic disorder)
   2. Active rheumatoid arthritis (a type of joint condition)

B. **If you have cystinuria, renewal also requires:**
   1. You have decreased urinary cysteine concentration (a type of lab test for a type of protein building block)

C. **If you have active rheumatoid arthritis, renewal also requires:**
   1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
   2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

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PENTOSAN POLYSULFATE

Generic	Brand				
PENTOSAN POLYSULFATE SODIUM	ELMIRON				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for approval:
You have interstitial cystitis (painful bladder condition)/bladder pain syndrome
You have experienced ongoing symptoms for at least six weeks
Therapy is prescribed by or in consultation with a urologist (a type of doctor who treats conditions affecting the organs in the body that make and remove urine)
You had a retinal (eye) exam or a detailed ophthalmic (eye) history performed/collected prior to starting therapy
You have tried or have a contraindication to (harmful for you to use) the following preferred agent: ONE guideline recommended alternative generic medication (such as amitriptyline, hydroxyzine, cimetidine)

RENEWAL CRITERIA

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for renewal:
You have interstitial cystitis (painful bladder condition)/bladder pain syndrome
You have experienced clinical improvement (observable improvement) from baseline (before treatment) due to treatment
You have NOT experienced any visual changes (change in how you see)/adverse effects (side effects) related to Elmiron

Effective: 04/01/26

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PERTUZUMAB

Generic	Brand				
PERTUZUMAB	PERJETA				

GUIDELINES FOR USE

Our guideline named **PERTUZUMAB (Perjeta)** requires the following rule(s) be met for approval:

You have breast cancer

Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive

If you have metastatic breast cancer (cancer that has spread to other parts of the body), approval also requires:

- You have not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease (treatment for cancer that has spread to other parts of the body)
- Perjeta will be used in combination with trastuzumab and docetaxel

If you have locally advanced (cancer that has spread to nearby tissue or lymph nodes), inflammatory, or early stage breast cancer (defined as either tumor is greater than 2 cm in diameter or node positive), approval also requires:

- Perjeta will be used in the neoadjuvant setting (given before main treatment)
- Perjeta will be used in combination with trastuzumab and chemotherapy (such as paclitaxel, carboplatin, or cyclophosphamide) as part of a complete drug regimen for early breast cancer

If you have early breast cancer, approval also requires:

- Your breast cancer is at high risk of recurrence (returning)
- Perjeta will be used in the adjuvant setting (given as add-on treatment)
- Perjeta will be used in combination with trastuzumab and chemotherapy (such as paclitaxel, carboplatin, or cyclophosphamide)

If you have unresectable or metastatic breast cancer (cancer that cannot be removed by surgery or has spread to other parts of the body), approval also requires:

- Your breast cancer is IHC 3+ or ISH positive, as determined by a Food and Drug Administration (FDA)-approved test
- You will use Perjeta in combination with fam-trastuzumab deruxtecan-nxki (Enhertu)

Effective: 01/19/26

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PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (NSA)

Generic	Brand				
PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	PHESGO				

GUIDELINES FOR USE

Our guideline named **PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (Phesgo)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:

- Locally advanced, inflammatory, or early breast cancer (tumor is greater than 2 cm in diameter or node positive)
- Early breast cancer at high risk of recurrence (returning)
- Metastatic breast cancer (breast cancer has spread to other parts of the body)

If you have locally advanced, inflammatory or early breast cancer (tumor is greater than 2 cm in diameter or node positive), approval also requires:

- Your breast cancer is HER2-positive
- The requested medication will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting (given before surgery)

If you have early breast cancer at high risk of recurrence, approval also requires:

- Your breast cancer is HER2-positive
- The requested medication will be used in combination with chemotherapy in the adjuvant setting (given as add-on treatment)

If you have metastatic breast cancer, approval also requires:

- Your breast cancer is HER2-positive
- You have not previously received anti-HER2 therapy or chemotherapy for metastatic disease
- The requested medication is being used in combination with docetaxel

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PEXIDARTINIB

Generic	Brand				
PEXIDARTINIB HYDROCHLORIDE	TURALIO				

GUIDELINES FOR USE

Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:

A. You have symptomatic tenosynovial giant cell tumor (TGCT: a type of non-cancerous growth in the soft tissue around a joint)
B. You are 18 years of age or older
C. TGCT is associated with severe morbidity (disease) or functional limitations
D. TGCT is NOT responsive to improvement with surgery

Effective: 02/01/26

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PHENOXYBENZAMINE

Generic	Brand			
PHENOXYBENZAMINE HCL	DIBENZYLINE, PHENOXYBENZA-MINE HCL			

GUIDELINES FOR USE

Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:

A. You have pheochromocytoma (a type of rare tumor)
B. The requested medication will be used before surgery to remove the tumor
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist-oncologist (a type of cancer doctor)
D. You have tried or have a contraindication to (harmful for you to use) an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, prazosin)

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PHENTERMINE - TOPIRAMATE

Generic	Brand				
PHENTERMINE/ TOPIRAMATE	QSYMIA, PHENTERMINE-TOPIRAMATE ER				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** requires the following rule(s) be met for approval:
The request is for weight loss or weight management
You are 12 years of age or older
You are actively enrolled in an exercise and caloric reduction program which may include use of an optional weight loss/behavioral modification program
If you are 18 years of age or older, approval also requires:
You meet ONE of the following before starting weight loss therapy:
You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
If you are 12 to 17 years of age, approval also requires:
Your initial body mass index (BMI: a tool for evaluating body fat) is in the 95th percentile or greater for age and sex

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PHENTERMINE - TOPIRAMATE

RENEWAL CRITERIA

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** requires the following rule(s) be met for renewal:

The request is for weight loss or weight management

If you are 12 to 17 years of age, approval also requires:

- You have achieved or maintained at least a 3% to 5% weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

If you are 18 years of age or older, approval also requires:

- You meet ONE of the following before starting weight loss therapy:
  - You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
  - You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
  - You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
  - You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
- You have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment

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PIMAVANSERIN

Generic	Brand				
PIMAVANSERIN TARTRATE	NUPLAZID				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:

A. You have psychosis (a type of mental health disorder) associated with Parkinson's disease (PD: a type of movement disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), geriatrician (a doctor who specializes in the health care of older adults), or behavioral health specialist (such as a psychiatrist [a type of mental health doctor])

RENEWAL CRITERIA

Our guideline named **PIMAVANSERIN (Nuplazid)** requires the following rule(s) be met for renewal:

A. You have experienced improvement in symptoms of psychosis (a type of mental health disorder) from baseline during the past 12 months of therapy, AND you show a continued need for treatment

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PIRFENIDONE

Generic	Brand				
PIRFENIDONE	ESBRIET, PIRFENIDONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:
You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
You do NOT have other known causes of interstitial lung disease (ILD: a type of lung condition) (such as connective tissue disease [a type of autoimmune disorder], drug toxicity, asbestos [a type of mineral that can be toxic] or beryllium [a type of metal that can be toxic] exposure, hypersensitivity pneumonitis [a type of lung condition], systemic sclerosis [a type of autoimmune disorder], rheumatoid arthritis [a type of joint condition], radiation, sarcoidosis [a type of inflammatory disorder], bronchiolitis obliterans organizing pneumonia [a type of lung condition], human immunodeficiency virus [HIV: an immune system disease caused by a virus] infection, viral hepatitis [type of liver inflammation], cancer)
You have a usual interstitial pneumonia pattern (UIP: a specific type of lung scarring) as shown by high-resolution computed tomography (HRCT: type of imaging test) alone or by a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
You do NOT currently smoke cigarettes
You will NOT use Esbriet concurrently (at the same time) with Ofev

RENEWAL CRITERIA

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:
You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
You will NOT use Esbriet concurrently (at the same time) with Ofev

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PIRTOBRUTINIB

Generic	Brand				
PIRTOBRUTINIB	JAYPIRCA				

GUIDELINES FOR USE

Our guideline named **PIRTOBRUTINIB (Jaypirca)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Relapsed or refractory mantle cell lymphoma (MCL) (a type of blood cancer that has returned or did not respond to treatment)
- Relapsed or refractory chronic lymphocytic leukemia (CLL) (a type of blood cancer that has returned or did not respond to treatment)
- Relapsed or refractory small lymphocytic lymphoma (SLL) (a type of blood cancer that has returned or did not respond to treatment)

If you have relapsed or refractory mantle cell lymphoma, approval also requires:

- You are 18 years of age or older
- You have previously received at least TWO lines of systemic therapy (treatment that targets the entire body), including a BTK inhibitor (Bruton tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

If you have relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:

- You are 18 years of age or older
- You have previously received a covalent BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

Effective: 01/12/26

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PITOLISANT

Generic	Brand				
PITOLISANT HCL	WAKIX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   2. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. **If you have excessive daytime sleepiness with narcolepsy, approval also requires:**
   1. You have narcolepsy (a type of sleep condition) that is confirmed by ONE of the following:
      a. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs: time it takes to enter dream sleep)
      b. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
      c. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have normal levels of a chemical that helps with staying awake)
   2. You have EDS lasting for at least 3 months and an Epworth Sleepiness Scale (ESS: tool to measure your sleepiness) score of more than 10
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   4. You will NOT use Wakix concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)

(Initial criteria continued on next page)

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) ONE preferred generic typical stimulant (such as amphetamine sulfate [Evekeo], methylphenidate [Ritalin])
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) one preferred generic typical stimulant (such as amphetamine sulfate [Evekeo], methylphenidate [Ritalin]) AND solriamfetol (Sunosi), armodafinil (Nuvigil), or modafinil (Provigil)

C. **If you have cataplexy with narcolepsy, approval also requires:**
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
   - A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
   - You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
   - You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
5. You will NOT use Wakix concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
6. You have tried TWO of the following preferred medications: venlafaxine, fluoxetine, a TCA (tricyclic antidepressant such as clomipramine, imipramine)

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PITOLISANT

RENEWAL CRITERIA

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   2. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. You will NOT use Wakix concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]

C. You meet ONE of the following:
   1. You have demonstrated at least a 25% improvement in Epworth Sleepiness Scale (ESS: tool to measure your sleepiness) scores compared to baseline
   2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline
   3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep) from baseline

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Effective: 08/28/26

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PIVMECILLINAM

Generic	Brand				
PIVMECILLINAM HCL	PIVYA				

GUIDELINES FOR USE

Our guideline named **PIVMECILLINAM (Pivya)** requires the following rule(s) be met for approval:
You have uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
You are 18 years of age or older
You are a female
You meet ONE of the following:
Therapy is prescribed by or in consultation with an Infectious Disease (ID) specialist (a doctor who specializes in the treatment of infections)
Therapy is a continuation of care from an inpatient setting
You meet ALL of the following:
a. There is a culture (a type of laboratory test) that shows your infection is caused by a multidrug-resistant (other medications did not work well) bacteria
b. Pivya will work against the bacteria from the culture
c. The bacteria is resistant (other medication did not work well), or you have a contraindication to (harmful for you to use) other beta-lactams medications (such as cefdinir, cefaclor), fluoroquinolone medications (such as ciprofloxacin, levofloxacin), cephalosporins, penicillins, nitrofurantoin, and sulfamethoxazole/trimethoprim medications

Effective: 02/09/26

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PLASMINOGEN

Generic	Brand				
PLASMINOGEN, HUMAN-TVMH	RYPLAZIM				

GUIDELINES FOR USE

Our guideline named **PLASMINOGEN (Ryplazim)** requires the following rule(s) be met for approval:
You have plasminogen deficiency type 1 (hypoplasminogenemia: a type of genetic condition)

Effective: 02/01/26

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PLERIXAFOR (NSA)

Generic	Brand			
PLERIXAFOR	MOZOBIL, PLERIXAFOR			

GUIDELINES FOR USE

Our guideline named **PLERIXAFOR (Mozobil)** requires you meet the following rule(s) for approval:

A. You have ONE of the following:
   1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   2. Multiple myeloma (MM: a type of blood cancer)
B. The requested medication will be used in combination with filgrastim or its biosimilars (such as Neupogen, Nivestym)
C. The requested medication will be used to mobilize hematopoietic stem cells to the peripheral blood for collection (a type of blood cell is stimulated to be collected from your blood) followed by autologous stem cell transplantation (a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

Effective: 10/09/23

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PLOZASIRAN

Generic	Brand				
PLOZASIRAN SODIUM	REDEMPLO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PLOZASIRAN (Redemplo)** requires the following rule(s) be met for approval:

G. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
H. You are 18 years of age or older
I. You will use Redemplo as an adjunct (add-on) therapy to diet
J. You will NOT use Redemplo concurrently (at the same time) with another medication (such as Tryngolza [olezarsen]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
K. Your familial chylomicronemia syndrome (FCS: a type of rare genetic condition) has been confirmed with ONE of the following:
    1. Genetic testing (a type of lab test)
    2. History of fasting triglycerides (a type of fat) of at least 1000 mg/dL on repeated testing (for at least 3 prior occasions) AND a history of recurrent acute pancreatitis (short-term inflammation of the pancreas) that is not caused by alcohol or cholelithiasis (hard, pebble-like stones that form inside gallbladder), a history of hospitalization for severe abdominal pain without other explainable cause, or a family history of hypertriglyceridemia-induced pancreatitis (high levels of fat in the blood due to pancreas inflammation)

RENEWAL CRITERIA

Our guideline named **PLOZASIRAN (Redemplo)** requires the following rule(s) be met for renewal:

A. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
B. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels
C. You will NOT use Redemplo concurrently (at the same time) with another medication (such as Tryngolza [olezarsen]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)

Effective: 08/28/26

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POLATUZUMAB VEDOTIN (NSA)

Generic	Brand			
POLATUZUMAB VEDOTIN-PIIQ	POLIVY			

GUIDELINES FOR USE

Our guideline named **POLATUZUMAB VEDOTIN-PIIQ (Polivy)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Relapsed (returned) or refractory (resistant to treatment) diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), not otherwise specified
   2. Previously untreated diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), not otherwise specified
   3. Previously untreated high-grade B-cell lymphoma (HGBL: an aggressive type of blood cancer)

B. **If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, approval also requires:**
   1. You are 18 years of age or older
   2. The requested drug will be used in combination with bendamustine and a rituximab product (type of cancer drug)
   3. You have had at least two prior therapies (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], tafasitamab with lenalidomide)
   4. You are not a candidate for an autologous hematopoietic stem cell transplant (cells transferred from your own body)

C. **If you have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified, approval also requires:**
   1. You are 18 years of age or older
   2. The requested drug will be used in combination with a rituximab product (type of cancer drug), cyclophosphamide, doxorubicin, and prednisone (R-CHP)

D. **If you have previously untreated high-grade B-cell lymphoma (HGBL), approval also requires:**
   1. You are 18 years of age or older
   2. You have International Prognostic Index (a tool used to determine the likely cause of a disease) score of 2 or greater
   3. The requested drug will be used in combination with a rituximab product (type of cancer drug), cyclophosphamide, doxorubicin, and prednisone (R-CHP)

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POMALIDOMIDE

Generic	Brand				
POMALIDOMIDE	POMALYST, POMALIDOMIDE				

GUIDELINES FOR USE

Our guideline named **POMALIDOMIDE (Pomalyst)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Multiple myeloma (MM: a type of blood cancer)
- Kaposi sarcoma (KS: a type of cancer in the lining of blood and lymph vessels)

If you have multiple myeloma, approval also requires:
- You are 18 years of age or older
- The requested medication will be used in combination with dexamethasone
- You have tried at least two prior treatments including Revlimid (lenalidomide) and a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])

If you have Kaposi sarcoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have acquired immunodeficiency syndrome (AIDS: a type of immune system disorder caused by virus infection)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV: a type of immune disorder])
  - You are human immunodeficiency virus (HIV)-negative

Effective: 02/28/26

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PONATINIB

Generic	Brand				
PONATINIB HCL	ICLUSIG				

GUIDELINES FOR USE

Our guideline named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Chronic myeloid leukemia (CML: type of blood cell cancer)
- Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

If you have chronic myeloid leukemia, approval also requires:
- You are 18 years of age or older
- You had a mutational analysis (a type of test) before starting therapy AND Iclusig is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile
- You meet ONE of the following:
  - You have T315I-positive (a genetic mutation) CML (chronic phase, accelerated phase, or blast phase)
  - You have chronic phase CML AND have a resistance to or are not able to safely use at least TWO prior kinase inhibitor treatments [such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]
  - You have accelerated phase or blast phase CML AND there are no other kinase inhibitors [such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] that can be used for your disease

If you have Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Your cancer is positive for the T315I mutation (a type of abnormal gene)
  - There are no other kinase inhibitors (such as Tasigna [nilotinib], Sprycel [dasatinib], Bosulif [bosutinib], Gleevec [imatinib]) that can be used for the treatment of your disease
  - You are newly diagnosed (such as you are starting or previously started Iclusig treatment at the time your condition was identified) AND Iclusig will be used in combination with chemotherapy

Effective: 08/11/25

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PONESIMOD

Generic	Brand				
PONESIMOD	PONVORY				

GUIDELINES FOR USE

Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), or active secondary progressive disease (advanced disease)

You are 18 years of age or older

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

You do NOT have any of the following contraindications to (harmful for you to use) Ponvory:

- Within the past 6 months, experienced a myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (TIA: short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- A presence of Mobitz Type II 2nd degree or 3rd degree AV block, sick sinus syndrome, or sino-atrial block (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)

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PORFIMER (NSA)

Generic	Brand			
PORFIMER SODIUM	PHOTOFRIN			

GUIDELINES FOR USE

Our guideline named **PORFIMER (Photofrin)** requires that the drug is being used for one of the following conditions:

The reduction of blockage and palliation of symptoms (treatment focused on relief from the symptoms and stress of a serious illness) in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC) or,

Treatment of microinvasive endobronchial non-small cell lung cancer (a type of lung cancer that involves airway blockage) where surgery and radiation therapy cannot be used; or

Helping to lessen your symptoms with completely obstructing or partially obstructing esophageal cancer, where in the opinion of your physician, you cannot be treated with Nd:YAG laser therapy (a high intensity laser that can be used to remove cancer) or,

The ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy (removal of precancerous cells of the esophagus and you did not have surgical treatment for esophageal cancer)

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POSACONAZOLE

Generic	Brand				
POSACONAZOLE	NOXAFIL, POSACONAZOLE				

GUIDELINES FOR USE

Our guideline named **POSACONAZOLE (Noxafil)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Continuation of therapy after hospital discharge
   2. Treatment of invasive aspergillosis (type of fungal infection)
   3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)
   4. Oropharyngeal candidiasis (OPC: fungal infection of the throat)
   5. Esophageal candidiasis (fungal infection in the tube connecting the throat and stomach)

B. **If the request is for treatment of invasive aspergillosis, approval also requires:**
   1. If the request is for posaconazole (Noxafil) tablets, approval also requires you meet the following:
      a. You are 2 years of age or older
   2. If the request is for posaconazole (Noxafil) PowderMix, approval also requires you meet ALL of the following:
      a. You are 2 to 17 years of age
      b. You have a contraindication to (harmful for you to use) or are unable to swallow tablets

C. **If the request is for prophylaxis of invasive aspergillus or candida infections, approval also requires:**
   1. You are at high risk of developing these infections due to being severely immunocompromised (such as hematopoietic stem cell transplant (HSCT: bone marrow transplant] recipients with graft-versus-host disease [GVHD: a type of immune disorder], hematologic malignancies [cancer affecting the blood] with prolonged neutropenia [low levels of a type of white blood cell] from chemotherapy [cancer treatment])
   2. If the request is for posaconazole (Noxafil) tablets, approval also requires you meet the following:
      a. You are 2 years of age or older

(Criteria continued on next page)

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

3. If the request is for posaconazole (Noxafil) oral suspension, approval also requires you meet ALL of the following:
   a. You are 13 years of age or older
   b. You have a contraindication to (harmful for you to use) or are unable to swallow tablets
4. If the request is for posaconazole (Noxafil) PowderMix, approval also requires you meet ALL of the following:
   a. You are 2 to 17 years of age
   b. You have a contraindication to (harmful for you to use) or are unable to swallow tablets

D. **If the request is for oropharyngeal candidiasis, approval also requires:**
1. You are 13 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: fluconazole, itraconazole
3. You are requesting posaconazole (Noxafil) oral suspension

E. **If the request is for esophageal candidiasis, approval also requires:**
1. You are 13 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) TWO of the following clinical standard of care medications: fluconazole, itraconazole solution, voriconazole

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POZELIMAB-BBFG (NSA)

Generic	Brand				
POZELIMAB-BBFG	VEOPOZ				

GUIDELINES FOR USE

Our guideline named **POZELIMAB-BBFG (Veopoz)** requires the following rule(s) be met for approval:

A. You have CD55-deficient protein-losing enteropathy (PLE, also known as CHAPLE disease [a rare genetic disorder])
B. You are 1 year of age or older

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PRALATREXATE (NSA)

Generic	Brand			
PRALATREXATE	FOLOTYN, PRALATREXATE			

GUIDELINES FOR USE

Our guideline named **PRALATREXATE (Folotyn)** requires the following rule(s) be met for approval:

You have relapsed or refractory peripheral T-cell lymphoma (PTCL: a type of blood cancer that has returned or did not fully respond to treatment)

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PRALSETINIB

Generic	Brand				
PRALSETINIB	GAVRETO				

GUIDELINES FOR USE

Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor, as detected by a Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor
   3. You need systemic therapy (treatment that targets the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is an appropriate treatment option)

Effective: 02/01/26

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PREGABALIN

Generic	Brand				
PREGABALIN	LYRICA, PREGABALIN				

GUIDELINES FOR USE

Our guideline named **PREGABALIN (Lyrica)** requires the following rule(s) be met for approval:

A. You have a contraindication to (harmful for you to use) or are unable to swallow generic pregabalin capsules

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PYRIMETHAMINE

Generic	Brand				
PYRIMETHAMINE	DARAPRIM, PYRIMETHAMINE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:

A. The request is ONE of the following:
   1. Acute (short-term) treatment of toxoplasmosis (a type of parasite infection)
   2. Chronic (long-term) maintenance therapy for toxoplasmosis
   3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
   4. Congenital toxoplasmosis (unborn baby infected with parasite from the mother)

B. **If you are being treated for acute toxoplasmosis, approval also requires:**
   1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor that specializes in treating infections)

C. **If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:**
   1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor that specializes in treating infections)
   2. You are also infected with human immunodeficiency virus (HIV: an immune system disease caused by a virus)
   3. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks

D. **If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:**
   1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor that specializes in treating infections)
   2. You are also infected with human immunodeficiency virus (HIV: an immune system disease caused by a virus)
   3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: Bactrim (sulfamethoxazole-trimethoprim)
   4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (you had a current or past infection with *Toxoplasma gondii)*
   5. Your CD4 count (a type of lab test) is less than 100 cells/mm(3)

E. **If you have congenital toxoplasmosis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric infectious disease specialist (a doctor that specializes in treating infections in children and adolescents)

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PYRIMETHAMINE

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:

A. The request is ONE of the following:
   1. Acute (short-term) treatment of toxoplasmosis (a type of parasite infection)
   2. Chronic (long-term) maintenance therapy for toxoplasmosis
   3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)

B. **If you are being treated for acute toxoplasmosis, renewal also requires:**
   1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

C. **If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: an immune system disease caused by a virus)
   2. Your CD4 count (a type of lab test) is less than 200 cells/mm(3)
   3. You are currently taking anti-retroviral therapy (ART: medications that treat HIV)

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QUIZARTINIB

Generic	Brand				
QUIZARTINIB DIHYDROCHLORIDE	VANFLYTA				

GUIDELINES FOR USE

Our guideline named **QUIZARTINIB (Vanflyta)** requires the following rule(s) be met for approval:
You have acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
You are 18 years of age or older
You are newly diagnosed (such as you are starting or previously started Vanflyta treatment at the time your condition was identified)
Your cancer is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD: a type of mutation) positive, as detected by a Food and Drug Administration (FDA)-approved test
You meet ONE of the following:
- Vanflyta will be used in combination with a standard cytarabine and anthracycline (such as daunorubicin, idarubicin) as induction therapy (a type of therapy to treat cancer), followed by use with cytarabine as consolidation therapy (type of therapy to treat cancer)
- Vanflyta will be used as maintenance monotherapy (one drug treatment) following consolidation chemotherapy

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RAMUCIRUMAB (NSA)

Generic	Brand			
RAMUCIRUMAB	CYRAMZA			

GUIDELINES FOR USE

Our guideline named **RAMUCIRUMAB (Cyramza)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:

- Advanced or metastatic (cancer that has spread to other parts of the body), gastric cancer or gastro-esophageal junction adenocarcinoma (cancer of the stomach or caner of the esophagus [tube that connects mouth and stomach])
- Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of your body)
- Metastatic colorectal cancer (type of rcolon or rectum cancer that has spread to other parts of the body)
- Hepatocellular carcinoma (type of liver cancer)

If you have advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, approval also requires:

The requested medication will be used as a single agent or in combination with paclitaxel

You have experienced disease progression (disease has worsened) on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) OR platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

If you have metastatic non-small cell lung cancer (NSCLC), approval also requires ONE of the following:

The requested medication will be used in combination with docetaxel and you meet ONE of the following:

- You have experienced disease progression (disease has worsened) on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin)
- You have an epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK : type of enzyme) genomic tumor abnormality AND your disease has gotten worse on an Food and Drug Administration (FDA)-approved therapy (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza

The requested medication will be used in combination with erlotinib as first-line treatment AND your tumors have epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 (L858R) substitution mutations

(Criteria continued on next page)

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GUIDELINE FOR USE (CONTINUED)

If you have metastatic colorectal cancer, approval also requires:
- The requested medication will be used in combination with FOLFIRI (drug combination of irinotecan, folinic acid, and 5-fluorouracil)
- You have experienced disease progression (disease has worsened) on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)

If you have hepatocellular carcinoma, approval also requires:
- The requested medication will be used as a single agent
- You have an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
- You have been treated with sorafenib (Nexavar)

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RANIBIZUMAB-EQRN

Generic	Brand				
RANIBIZUMAB-EQRN	CIMERLI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RANIBIZUMAB-EQRN (Cimerli)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Myopic choroidal neovascularization (mCNV: a type of eye condition)

If you have neovascular (wet) age-related macular degeneration, approval also requires:

- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If you have macular edema following retinal vein occlusion, approval also requires:

- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

If you have diabetic macular edema, approval also requires:

- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

If you have myopic choroidal neovascularization, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist

RENEWAL CRITERIA

NOTE: For the diagnosis of myopic choroidal neovascularization (mCNV), please refer to the Initial Criteria section.

Our guideline named **RANIBIZUMAB-EQRN (Cimerli)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If you have macular edema following retinal vein occlusion, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

(Renewal criteria continued on next page)

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RANIBIZUMAB-EQRN

RENEWAL CRITERIA (CONTINUED)

If you have diabetic macular edema, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

If you have diabetic retinopathy, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

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RANIBIZUMAB-LUCENTIS

Generic	Brand				
RANIBIZUMAB	LUCENTIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RANIBIZUMAB-LUCENTIS** requires the following rule(s) be met for approval:

You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Myopic choroidal neovascularization (mCNV: a type of eye condition)

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If you have macular edema following retinal vein occlusion, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

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RANIBIZUMAB-LUCENTIS

INITIAL CRITERIA (CONTINUED)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

If you have myopic choroidal neovascularization, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist

RENEWAL CRITERIA

NOTE: For the diagnosis of myopic choroidal neovascularization (mCNV), please refer to the Initial Criteria section.

Our guideline named **RANIBIZUMAB-LUCENTIS** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

(Renewal criteria continued on next page)

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RANIBIZUMAB-LUCENTIS

RENEWAL CRITERIA (CONTINUED)

If you have macular edema following retinal vein occlusion, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

If you have diabetic macular edema, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

If you have diabetic retinopathy, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

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RANIBIZUMAB-NUNA

Generic	Brand				
RANIBIZUMAB-NUNA	BYOOVIZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RANIBIZUMAB-NUNA (Byooviz)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Myopic choroidal neovascularization (mCNV: a type of eye condition)

If you have neovascular (wet) age-related macular degeneration, approval also requires:

- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

If you have macular edema following retinal vein occlusion, approval also requires:

- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

If you have diabetic macular edema, approval also requires:

- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

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RANIBIZUMAB-NUNA

INITIAL CRITERIA (CONTINUED)

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

If you have myopic choroidal neovascularization, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist

RENEWAL CRITERIA

NOTE: For the diagnosis of myopic choroidal neovascularization (mCNV), please refer to the Initial Criteria section.

Our guideline named **RANIBIZUMAB-NUNA (Byooviz)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

If you have macular edema following retinal vein occlusion, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

(Renewal criteria continued on next page)

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RANIBIZUMAB-NUNA

RENEWAL CRITERIA (CONTINUED)

If you have diabetic macular edema, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

If you have diabetic retinopathy, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

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RANIBIZUMAB-SUSVIMO

Generic	Brand				
RANIBIZUMAB, RANIBIZUMAB/INIT FILL NEEDLE	SUSVIMO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RANIBIZUMAB (Susvimo)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

If you have neovascular (wet) age-related macular degeneration, approval also requires:

- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
- You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of neovascular (wet) age-related macular degeneration

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RANIBIZUMAB-SUSVIMO

INITIAL CRITERIA (CONTINUED)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
- You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
- You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

RENEWAL CRITERIA

Our guideline named **RANIBIZUMAB (Susvimo)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of neovascular (wet) age-related macular degeneration

(Renewal criteria continued on next page)

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RANIBIZUMAB-SUSVIMO

RENEWAL CRITERIA (CONTINUED)

If you have diabetic macular edema, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

If you have diabetic retinopathy, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

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RAVULIZUMAB-CWVZ

Generic	Brand				
RAVULIZUMAB-CWVZ	ULTOMIRIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

Ultomiris (ravulizumab-cwvz) is NOT being used for the treatment of hemolytic uremic syndrome related to Shiga toxin E. coli (a bacteria)

If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
- You are 1 month of age or older
- Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
- You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
- You will NOT use Ultomiris concurrently (at the same time) with C5 complement inhibitor therapy (such as Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

If you have atypical hemolytic uremic syndrome, approval also requires:
- You are 1 month of age or older

(Initial criteria continued on next page)

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RAVULIZUMAB-CWVZ

INITIAL CRITERIA (CONTINUED)

If you have generalized myasthenia gravis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
- You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
- You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
- You have tried or have a contraindication to ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)
- You will NOT use Ultomiris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
  - You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

If you have neuromyelitis optica spectrum disorder (NMOSD), approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
- You are positive for anti-aquaporin-4 (AQP4: a type of protein) antibodies
- You will NOT use Ultomiris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])
- You have at least ONE of the following core clinical characteristics:
  - Optic neuritis (a type of brain disorder)
  - Acute myelitis (a type of brain disorder)
  - Area postrema syndrome (a type of brain disorder)
  - Acute brainstem syndrome (a type of brain disorder)
  - Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

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RAVULIZUMAB-CWVZ

RENEWAL CRITERIA

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
- Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
- Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
- You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before treatment)
- You will NOT use Ultomiris concurrently (at the same time) with C5 complement inhibitor therapy (such as Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

If you have generalized myasthenia gravis, renewal also requires:
- You have experienced a clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
- You will NOT use Ultomiris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

If you have neuromyelitis optica spectrum disorder, renewal also requires:
- You have experienced a clinical benefit (reduction in relapse frequency compared to baseline [before treatment] or a decrease in NMOSD-related hospitalizations)
- You will NOT use Ultomiris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

Effective: 02/01/26

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REGORAFENIB

Generic	Brand				
REGORAFENIB	STIVARGA				

GUIDELINES FOR USE

Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic colorectal cancer (CRC: a type of digestive cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that has spread from where it started to nearby tissue or lymph nodes, unable to remove by surgery, or has spread to other parts of the body)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine
   2. You had previous treatment with an anti-VEGF therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept)
   3. If you have RAS wild-type (a type of unmutated gene) metastatic colorectal cancer, approval also requires you had previous treatment with an anti-EGFR therapy such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

D. **If you have hepatocellular carcinoma, approval also requires:**
   1. You had previous treatment with Nexavar (sorafenib)

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RELACORILANT

Generic	Brand				
RELACORILANT	LIFYORLI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RELACORILANT (Lifyorli)** requires the following rule(s) be met for approval:
You have epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers)
You are 18 years of age or older
Your cancer is platinum-resistant (resistant to medications such as paclitaxel, docetaxel, cisplatin, carboplatin)
Lifyorli will be used in combination with nab-paclitaxel
You have received at least one to three prior systemic treatment regimens (treatment that targets the entire body), at least one of which included bevacizumab

RENEWAL CRITERIA

Our guideline named **RELACORILANT (Lifyorli)** requires the following rule(s) be met for renewal:
You have epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers)
You have shown clinical benefit (radiographic [imaging] response, stable disease)
You will continue nab-paclitaxel therapy

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RELUGOLIX

Generic	Brand				
RELUGOLIX	ORGOVYX				

GUIDELINES FOR USE

Our guideline named **RELUGOLIX (Orgovyx)** requires the following rule(s) be met for approval:
You have advanced prostate cancer (a type of cancer that has spread to other parts of the body)
You are 18 years of age or older

Effective: 02/01/26

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

Generic	Brand				
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Oriahnn [elagolix/estradiol/norethindrone], Lupron Depot [leuprolide])
   5. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
   5. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

RENEWAL CRITERIA

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), renewal also requires:**
   1. You had improvement of heavy menstrual bleeding on therapy
   2. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Oriahnn [elagolix/estradiol/norethindrone], Lupron Depot [leuprolide])
   3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, renewal also requires:**
   1. You have had improvement in pain related to endometriosis (condition affecting the uterus) while on therapy
   2. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
   3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

Effective: 08/07/26

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REMIBRUTINIB

Generic	Brand				
REMIBRUTINIB	RHAPSIDO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **REMIBRUTINIB (Rhapsido)** requires the following rule(s) be met for approval:

You have chronic spontaneous urticaria (CSU) (also called chronic idiopathic urticaria [CIU]) [severe itching with unknown cause]

You are 18 years of age or older

Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)

You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks

You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), 4-times the maximally labeled dose of a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)

You will NOT use Rhapsido concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) [severe itching with unknown cause]

You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: Dupixent (dupilumab), Xolair (omalizumab)

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REMIBRUTINIB

RENEWAL CRITERIA

Our guideline named **REMIBRUTINIB (Rhapsido)** requires the following rule(s) be met for renewal:

You have chronic spontaneous urticaria (CSU) (also called chronic idiopathic urticaria [CIU]) [severe itching with unknown cause]

Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)

You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])

You will NOT use Rhapsido concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) [severe itching with unknown cause]

Effective: 01/01/26

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REPOTRECTINIB

Generic	Brand				
REPOTRECTINIB	AUGTYRO				

GUIDELINES FOR USE

Our guideline named **REPOTRECTINIB (Augtyro)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   2. Solid tumors

B. **If you have non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have *ROS1*-positive (abnormal change in a type of gene) tumors

C. **If you have solid tumors, approval also requires:**
   1. You are 12 years of age and older
   2. Your tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (abnormal change in a type of gene)
   3. Yours tumors are locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body), OR surgical resection (removal by surgery) is likely to result in severe morbidity (illness)
   4. You have progressed following treatment OR have no satisfactory alternative (other) therapy

Effective: 08/01/24

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RESLIZUMAB (NSA)

Generic	Brand				
RESLIZUMAB	CINQAIR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for approval:
- You have severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
- You have a blood eosinophil (a type of white blood cell) level of at least 150 cells/mcL within the past 12 months
- Cinqair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
- You will NOT use Cinqair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)
- You meet ONE of the following:
  - You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months:
  - You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
  - You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
    - Daytime asthma symptoms more than twice per week
    - Any night waking due to asthma
    - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
    - Any activity limitation due to asthma

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RESLIZUMAB (NSA)

RENEWAL CRITERIA

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for renewal:

You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)

You will NOT use Cinqair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

You have shown a clinical response as evidenced by ONE of the following:

- You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline
- You have decreased your use of rescue medications (such as albuterol)
- You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Cinqair)
- You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

Effective: 01/01/25

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RESMETIROM

Generic	Brand				
RESMETIROM	REZDIFFRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for approval:

A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
B. You are 18 years of age or older
C. You do NOT have cirrhosis (liver damage and scarring)
D. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or endocrinologist (a type of hormone doctor)
E. You are enrolled in or have already completed a lifestyle intervention (such as dietary, exercise, psychology)
F. You will NOT use Rezdiffra concurrently (at the same time) with Wegovy for the treatment of non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
G. You have had a biopsy (removal of cells or tissue from the body for examination) or non-invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) in the past 12 months which shows you have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)
H. **If Wegovy is covered by your plan, approval also requires:**
    1. You have tried or have a contraindication to (harmful for you to use) Wegovy

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RESMETIROM

RENEWAL CRITERIA

Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for renewal:

A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
B. Your disease is stable or has improved from baseline (before treatment with Rezdiffra)
C. You will NOT use Rezdiffra concurrently (at the same time) with Wegovy for the treatment of non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
D. You have had a biopsy (removal of cells or tissue from the body for examination) or non-invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) which shows you have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)

Effective: 06/01/26

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RETIFANLIMAB-DLWR

Generic	Brand				
RETIFANLIMAB-DLWR	ZYNYZ				

GUIDELINES FOR USE

Our guideline named **RETIFANLIMAB-DLWR (Zynyz)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Metastatic or recurrent locally advanced Merkel cell carcinoma (MCC: a type of skin cancer that has spread to other parts of the body or has returned and spread from where it started to nearby tissue or lymph nodes)
- Locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC: a type of cancer of the anal canal that has returned from where it started or has spread to other parts of the body)

If you have metastatic or recurrent locally advanced Merkel cell carcinoma, approval also requires:

You are 18 years of age or older

If you have locally recurrent or metastatic squamous cell carcinoma of the anal canal, approval also requires:

You are 18 years of age or older

You meet ONE of the following:

- Zynyz will be used in combination with carboplatin and paclitaxel AND your cancer is inoperable (not able to operate on)
- Zynyz will be used as a single agent (used alone) AND your disease has progressed (worsened) while on platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin) or you are intolerant (side effects) to platinum-based chemotherapy

Effective: 04/29/26

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REVUMENIB

Generic	Brand				
REVUMENIB CITRATE	REVUFORJ				

GUIDELINES FOR USE

Our guideline named **REVUMENIB (Revuforj)** requires the following rule(s) be met for approval:
You have relapsed or refractory acute leukemia (a type of blood cancer that has returned or did not respond to treatment)
You are 1 year of age or older
You meet ONE of the following:
- You have a lysine methyltransferase 2A gene (KMT2A) translocation (a type of gene abnormality), as determined by a Food and Drug Administration (FDA)-authorized test
- You have a susceptible nucleophosmin 1 (NPM1) mutation (an abnormal change in gene) AND you have no satisfactory alternative treatment options

Effective: 12/01/25

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REZAFUNGIN (NSA)

Generic	Brand				
REZAFUNGIN ACETATE	REZZAYO				

GUIDELINES FOR USE

Our guideline named **REZAFUNGIN (Rezzayo)** requires the following rule(s) be met for approval:

A. The request is for the treatment of candidemia (a type of fungal infection) or invasive candidiasis (a type of fungal infection)
B. You are 12 years of age or older
C. You have limited or no alternative treatment options

Effective: 07/31/26

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RIBOCICLIB

Generic	Brand			
RIBOCICLIB SUCCINATE	KISQALI			

GUIDELINES FOR USE

Our guideline named **RIBOCICLIB (Kisqali)** requires the following rule(s) be met for approval:
You have breast cancer
Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
You meet ONE of the following:
- You have stage II or III early breast cancer (initial stage of cancer); you will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) for adjuvant (add-on) treatment; AND you are at high risk of recurrence (disease returning)
- You have advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body), and you meet ONE of the following:
  - You will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) as initial endocrine (hormone)-based therapy
  - You will use Kisqali in combination with fulvestrant (Faslodex), as initial endocrine (hormone)-based therapy or following disease progression (your condition worsened) on endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)

Effective: 05/05/25

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RIBOCICLIB-LETROZOLE

Generic	Brand				
RIBOCICLIB SUCCINATE/ LETROZOLE	KISQALI FEMARA CO-PACK				

GUIDELINES FOR USE

Our guideline named **RIBOCICLIB-LETROZOLE (Kisqali Femara Co-Pack)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Stage II or III early breast cancer (initial stage of breast cancer)
   2. Advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)

B. **If you have stage II or III early breast cancer, approval also requires:**
   1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   2. Kisqali Femara Co-Pack will be used for adjuvant (add-on) treatment
   3. You are at high risk of recurrence (disease returning)

C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   2. Kisqali Femara Co-Pack will be used as initial endocrine (hormone)-based therapy

Effective: 10/21/24

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RIFAXIMIN 200MG

Generic	Brand				
RIFAXIMIN	XIFAXAN				

GUIDELINES FOR USE

Our guideline named **RIFAXIMIN 200MG (Xifaxan)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Travelers' diarrhea
- Overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage)
- *Clostridium difficile* infection (a type of bacterial infection)

If you have travelers' diarrhea, approval also requires:
- You are 12 years of age or older
- You have tried or have a contraindication to (harmful for you to use) oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

If you have overt hepatic encephalopathy, approval also requires:
- Xifaxan will be used in combination with lactulose

If you have *Clostridium difficile* infection, approval also requires:
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
- You had at least one previous occurrence of *Clostridium difficile* infection
- You have been treated with vancomycin for the current *Clostridium difficile* infection

Effective: 12/01/25

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RILONACEPT

Generic	Brand				
RILONACEPT	ARCALYST				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for approval:

You meet ONE of the following:

- You have Cryopyrin-Associated Periodic Syndromes (CAPS: a type of immune disorder) including, Familial Cold Autoinflammatory Syndrome (FCAS: a type of immune disorder) or Muckle-Wells Syndrome (MWS: a type of gene disorder)
- You have Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a type of immune system disorder)
- Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)

If you have Cryopyrin-Associated Periodic Syndromes including Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:

- You are 12 years of age or older
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
- You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
- You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes (a type of immune system disorder)

(Initial criteria continued on next page)

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RILONACEPT

INITIAL CRITERIA (CONTINUED)

If you have Deficiency of Interleukin-1 Receptor Antagonist, approval also requires:
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body])
- You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: fungal infection of toenail)
- You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (a type of immune system disorder)

If the request is for the treatment or reduction in risk of recurrent pericarditis, approval also requires:
- You are 12 years of age or older
- You had an episode of acute pericarditis (a type of short-term heart condition)
- You have been symptom-free for 4 to 6 weeks
- You have TWO of the following: chest pain consistent with pericarditis, pericardial friction rub (a type of heart condition), electrocardiogram (ECG: a type of lab test) showing diffuse ST-segment elevation or PR-segment depression (an abnormal heart test), and new or worsening pericardial effusion (a type of heart condition)
- You have tried or have a contraindication to (harmful for you to use) the following clinical standard of care medications: two NSAIDS (non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin) AND colchicine
- You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of recurrent pericarditis (a type of heart condition that returns)

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RILONACEPT

RENEWAL CRITERIA

NOTE: For the diagnoses of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), or Deficiency of Interleukin-1 Receptor Antagonist (DIRA), please refer to the Initial Criteria section.

Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for renewal:

Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)

You have had a reduction in pericarditis recurrence (a type of heart condition that has come back less often) or improvement in symptoms

You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of recurrent pericarditis (a type of heart condition that returns)

Effective: 04/01/26

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RILUZOLE

Generic	Brand				
RILUZOLE	EXSERVAN, TIGLUTIK				

GUIDELINES FOR USE

Our guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:
You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
You are 18 years of age or older
You have tried the preferred medication: riluzole tablets
You are unable to take riluzole tablet formulation

Effective: 03/04/26

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RILZABRUTINIB

Generic	Brand				
RILZABRUTINIB	WAYRILZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RILZABRUTINIB (Wayrilz)** requires the following rule(s) be met for approval:
You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
You have a platelet (a type of blood cell) count of less than 30 x 10^9/L, OR you have a platelet count of less than 50 x 10^9/L and had a prior bleeding event
You have tried or have a contraindication to (harmful for you to use) a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib]) OR a thrombopoietin receptor agonist (such as Doptelet [avatrombopag], Promacta [eltrombopag])
You will NOT use Wayrilz concurrently (at the same time) with a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

RENEWAL CRITERIA

Our guideline named **RILZABRUTINIB (Wayrilz)** requires the following rule(s) be met for renewal:
You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline OR a decrease in bleeding events
You will NOT use Wayrilz concurrently (at the same time) with a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

Effective: 10/01/25

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RIMABOTULINUM TOXIN B (NSA)

Generic	Brand				
RIMABOTULINUM TOXIN B	MYOBLOC				

GUIDELINES FOR USE

Our guideline named **RIMABOTULINUM TOXIN B (Myobloc)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
Cervical dystonia (a type of muscle condition)
Chronic sialorrhea (drooling or excessive salivation)
You are 18 years of age or older

NOTE: This medication will not be approved for a cosmetic indication (for example wrinkles - glabellar lines, lateral canthal lines, forehead lines).

Effective: 11/01/22

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RIMEGEPANT

Generic	Brand				
RIMEGEPANT SULFATE	NURTEC ODT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:

The request is for ONE of the following:

- Acute (quick onset) treatment of migraines (a type of headache)
- Preventive treatment of episodic migraines (a type of headache)

If the request is for the acute treatment of migraines, approval also requires:

- You are 18 years of age or older
- You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute (quick onset) treatment of migraines (a type of headache)
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

If the request is for the preventive treatment of episodic migraines (0-14 headache days per month), approval also requires:

- You are 18 years of age or older
- You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine (a type of headache) prevention

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RIMEGEPANT

RENEWAL CRITERIA

NOTE: For the diagnosis of acute treatment of migraines, please refer to the Initial Criteria section.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

The request is the preventive treatment of episodic migraines (a type of headache, 0-14 headache days per month):

You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine (a type of headache) prevention

You meet ONE of the following:

- You have experienced a reduction in migraine or headache frequency of at least 2 days per month
- You have experienced a reduction in migraine severity
- You have experienced a reduction in migraine duration

Effective: 04/01/26

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RIOCIGUAT

Generic	Brand				
RIOCIGUAT	ADEMPAS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)

B. **If you have pulmonary arterial hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   4. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

C. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. You have persistent or recurrent disease after surgical treatment (condition continues to exist or returns after surgery) OR you are not a candidate for surgery OR you have inoperable (not able to operate on) chronic thromboembolic pulmonary hypertension
   4. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   5. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

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RIOCIGUAT

RENEWAL CRITERIA

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)
   2. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

Effective: 07/01/24

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RIPRETINIB

Generic	Brand				
RIPRETINIB	QINLOCK				

GUIDELINES FOR USE

Our guideline named **RIPRETINIB (Qinlock)** requires the following rule(s) be met for approval:
You have advanced gastrointestinal stromal tumor (GIST: a type of digestive system cancer)
You are 18 years of age or older
You have received prior treatment with at least THREE kinase inhibitors (such as Sutent [sunitinib], Ayvakit [avapritinib], Stivarga [regorafenib]), including Gleevec (imatinib)

Effective: 02/01/26

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RISANKIZUMAB-RZAA

Generic	Brand				
RISANKIZUMAB-RZAA	SKYRIZI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Skyrizi
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp

(Initial criteria continued on next page)

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   4. You are 18 years of age or older
   5. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   6. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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RISDIPLAM

Generic	Brand				
RISDIPLAM	EVRYSDI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:

A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
B. Therapy is prescribed by or in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
C. Your diagnosis is confirmed by a gene mutation (abnormal change) analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
D. **If you are pre-symptomatic (symptoms have not yet appeared), approval also requires:**
    1. You have up to (no more than) THREE copies of the survival motor neuron 2 (SMN2: type of protein) gene based on a screening that was done when you were a newborn
E. **If you are symptomatic (symptoms have appeared), approval also requires:**
    1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
    2. You had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
    3. If you have received prior gene therapy, you experienced a less than expected clinical benefit with gene therapy

RENEWAL CRITERIA

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:

A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
B. You meet ONE of the following:
    1. You have improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    2. You have improved, maintained, or demonstrated a less than expected decline in other muscle function (such as pulmonary [lung/breathing] function)

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RITLECITINIB

Generic	Brand				
RITLECITINIB TOSYLATE	LITFULO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for approval:

A. You have severe alopecia areata (a type of hair loss)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have experienced at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool), for at least 6 months
E. You will NOT use Litfulo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Olumiant (baricitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

RENEWAL CRITERIA

Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for renewal:

A. You have severe alopecia areata (a type of hair loss)
B. You have shown improvement while on therapy (such as scalp hair coverage)
C. You will NOT use Litfulo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Olumiant (baricitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

Effective: 03/17/25

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RITUXIMAB

Generic	Brand				
RITUXIMAB	RITUXAN				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   3. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   4. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   5. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   6. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   7. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   8. Rituxan will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have non-Hodgkin's lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin’s lymphoma (a type of blood cancer)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:**
   1. You are 6 months to 17 years of age
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Rituxan will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
   4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)
   5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

E. **If you have chronic lymphocytic leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Rituxan will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
   4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)
   5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

F. **If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:**
   1. You are 2 years of age or older
   2. Rituxan will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
   3. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

G. **If you have moderate to severe pemphigus vulgaris, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

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RITUXIMAB

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy
C. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        a. Enbrel (etanercept)
        b. Adalimumab-ryvk/adalimumab-aaty
        c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RITUXIMAB-ABBS

Generic	Brand				
RITUXIMAB-ABBS	TRUXIMA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   3. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   4. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   5. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   7. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   8. Truxima will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. **If you have non-Hodgkin's lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin’s lymphoma (a type of blood cancer)

C. **If you have chronic lymphocytic leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Truxima will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
   4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)

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INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to clinical standard of care medication: a ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   6. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INITIAL CRITERIA (CONTINUED)

E. **If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:**
   1. You are 2 years of age or older
   2. Truxima will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
   3. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)

F. **If you have moderate to severe pemphigus vulgaris, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)

G. **If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:**
   1. You are 6 months to 17 years of age
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Truxima will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
   4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)

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RITUXIMAB-ABBS

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
C. You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        a. Enbrel (etanercept)
        b. Adalimumab-ryvk/adalimumab-aaty
        c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RITUXIMAB-ARRX

Generic	Brand				
RITUXIMAB-ARRX	RIABNI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   3. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   4. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   5. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   7. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   8. Riabni will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. **If you have non-Hodgkin's lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma (a type of blood cancer)

C. **If you have chronic lymphocytic leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Riabni will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
   4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

D. **If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:**
   1. You are 2 years of age or older
   2. Riabni will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
   3. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)

E. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   6. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

F. **If you have moderate to severe pemphigus vulgaris, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)

G. **If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:**
   1. You are 6 months to 17 years of age
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Riabni will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
   4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-ARRX

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
C. You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        i. Enbrel (etanercept)
        ii. Adalimumab-ryvk/adalimumab-aaty
        iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ

Generic	Brand				
RITUXIMAB/ HYALURONIDASE, HUMAN	RITUXAN HYCELA				

GUIDELINES FOR USE

Our guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Follicular lymphoma (FL: a type of blood cancer)
   2. Diffuse large B-cell lymphoma (DLBCL: a type of blood cancer)
   3. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   4. Rituxan Hycela will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. **If you have follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
   3. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of follicular lymphoma
   4. You meet ONE of the following:
      a. You have relapsed or refractory follicular lymphoma (cancer that has returned or does not fully respond to treatment)
      b. You have previously untreated follicular lymphoma AND Rituxan Hycela will be used in combination with chemotherapy (a type of cancer treatment, such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CVP [cyclophosphamide, vincristine, prednisone])
      c. You have achieved a complete or partial response to rituximab in combination with chemotherapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
      d. You have non-progressing (including stable disease) follicular lymphoma (cancer that is not worsening), AND Rituxan Hycela will be used after cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ

GUIDELINES FOR USE (CONTINUED)

C. **If you have diffuse large B-cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
   3. You have not been previously treated for diffuse large B-cell lymphoma
   4. Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or another anthracycline-based chemotherapy regimen (a type of cancer treatment)
   5. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma

D. **If you have chronic lymphocytic leukemia (CLL), approval also requires:**
   1. You are 18 years of age or older
   2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
   3. Rituxan Hycela will be used in combination with fludarabine and cyclophosphamide (FC)
   4. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

Effective: 03/10/25

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RITUXIMAB-PVVR

Generic	Brand				
RITUXIMAB-PVVR	RUXIENCE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   3. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   4. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   5. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   7. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt-like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   8. Ruxience will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. **If you have non-Hodgkin's lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma (a type of blood cancer)

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have chronic lymphocytic leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Ruxience will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
   4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)

D. **If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:**
   1. You are 2 years of age or older
   2. Ruxience will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
   3. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)

E. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE standard of care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use)TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

F. **If you have moderate to severe pemphigus vulgaris, approval also requires:**
   1. You are 18 years of age or older
   2. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)

G. **If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:**
   1. You are 6 months to 17 years of age
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Ruxience will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
   4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)

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RITUXIMAB-PVVR

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
C. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        a. Enbrel (etanercept)
        b. Adalimumab-ryvk/adalimumab-aaty
        c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ROFLUMILAST 0.3% CREAM

Generic	Brand				
ROFLUMILAST	ZORYVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have plaque psoriasis (a type of skin condition)
B. You are 2 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
    1. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
    2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
    3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    4. Topical retinoid (such as tazarotene cream/gel)
    5. Anthralin

RENEWAL CRITERIA

Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have plaque psoriasis (a type of skin condition)
B. You have achieved or maintained clear or minimal disease

Effective: 07/15/26

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ROFLUMILAST 0.05% CREAM

Generic	Brand				
ROFLUMILAST	ZORYVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROFLUMILAST 0.05% CREAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You are 2 to 5 years of age
C. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
    2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

RENEWAL CRITERIA

Our guideline named **ROFLUMILAST 0.05% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

Effective: 05/28/26

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ROFLUMILAST 0.15% CREAM

Generic	Brand				
ROFLUMILAST	ZORYVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You are 6 years of age or older
C. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
    2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

RENEWAL CRITERIA

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

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Effective: 05/28/26

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ROFLUMILAST - FOAM

Generic	Brand				
ROFLUMILAST	ZORYVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Seborrheic dermatitis (a type of skin condition)
   2. Plaque psoriasis (a type of skin condition)

B. **If you have seborrheic dermatitis, approval also requires:**
   1. You are 9 years of age or older
   2. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
         ii. Topical antifungal (such as ketoconazole, ciclopirox)
         iii. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
      b. You previously had a successful treatment with roflumilast foam

C. **If you have plaque psoriasis, approval also requires:**
   1. You are 12 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications:
      a. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
      b. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)

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ROFLUMILAST - FOAM

RENEWAL CRITERIA

NOTE: For the diagnosis of seborrheic dermatitis, please refer to the Initial Criteria section.

Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for renewal:

C. You have plaque psoriasis (a type of skin condition)
D. Your plaque psoriasis (a type of skin condition) involves the scalp and/or body
E. You have achieved or maintained clear or minimal disease

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ROMIDEPSIN (NSA)

Generic	Brand			
ROMIDEPSIN	ISTODAX			

GUIDELINES FOR USE

Our guideline named **ROMIDEPSIN (Istodax)** requires the following rule(s) be met for approval:
You have cutaneous T-cell lymphoma (CTCL: type of cancer that affects a certain type of immune system cells) also known as Mycosis Fungoides/Sezary Syndrome
You are 18 years of age or older
You meet ONE of the following:
- You had a trial of Zolinza (vorinostat) unless there is a medical reason why you cannot (contraindication) AND you are not able to tolerate oral medications
- You have tried at least one form of systemic therapy (such as retinoids, interferon, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) AND you are able to tolerate oral medications

Effective: 08/30/21

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ROMIPLOSTIM

Generic	Brand				
ROMIPLOSTIM	NPLATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have immune thrombocytopenia (ITP: a type of blood disorder)
   2. You will be using Nplate to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

B. **If you have immune thrombocytopenia, approval also requires:**
   1. You are 1 to 17 years of age with immune thrombocytopenia (ITP: a type of blood disorder) for at least 6 months, OR you are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
   3. You will NOT use Nplate concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Promacta [eltrombopag], Alvaiz [eltrombopag])
   4. You meet ONE of the following:
      c. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
      d. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND a prior bleeding event

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ROMIPLOSTIM

RENEWAL CRITERIA

NOTE: If the request is to increase survival in a patient acutely exposed to myelosuppressive doses of radiation, please refer to the Initial Criteria section.

Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for renewal:

A. You have immune thrombocytopenia (ITP: a type of blood disorder)
B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Nplate) OR a decrease in bleeding events
C. You will NOT use Nplate concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Promacta [eltrombopag], Alvaiz [eltrombopag])

Effective: 07/29/26

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ROMOSOZUMAB-AQQG (NSA)

Generic	Brand			
ROMOSOZUMAB-AQQG	EVENITY			

GUIDELINES FOR USE

Our guideline named **ROMOSOZUMAB-AQQG (Evenity)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak and brittle bones)
B. You have not received a total of 12 months or more of Evenity therapy
C. You meet ONE of the following criteria:
   1. You are at high risk for fractures defined as ONE of the following:
      History of osteoporotic (fragility, low trauma) fracture(s)
      2 or more risk factors for fracture such as history of multiple recent low trauma fractures, bone marrow density [BMD] T-score (measurement of how high your risk for osteoporosis is) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.
      No prior treatment for osteoporosis AND FRAX score (test for your risk of fractures) greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
   2. You are unable to use oral therapy. Reasons include upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine
   3. You had an adequate trial of, intolerance to, or a contraindication to (medical reason why you cannot use) bisphosphonates such as Fosamax, Actonel, Boniva

Effective: 04/10/23

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ROPEGINTERFERON ALFA-2B-NJFT

Generic	Brand				
ROPEGINTERFERON ALFA-2B-NJFT	BESREMI				

GUIDELINES FOR USE

Our guideline named **ROPEGINTERFERON ALFA-2B-NJFT (Besremi)** requires the following rule(s) be met for approval:
You have polycythemia vera (a type of blood cancer)
You are 18 years of age or older

Effective: 08/01/26

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ROSUVASTATIN

Generic	Brand				
ROSUVASTATIN CALCIUM	EZALLOR SPRINKLE				

GUIDELINES FOR USE

Our guideline named **ROSUVASTATIN (Ezallor Sprinkle)** requires the following rule(s) be met for approval:

A. You have a contraindication to (harmful for you to use) or are unable to swallow rosuvastatin oral tablets
B. **Requests for zero-dollar cost share also requires the following:**
   1. You are between 40 to 75 years old
   2. The requested quantity is within the low to moderate intensity daily dosage of 5mg to 10mg
   3. You are NOT concurrently (at the same time) taking any of the following secondary prevention medications for cardiovascular disease (heart disease):
      a. Aspirin/dipyridamole (Aggrenox)
      b. Clopidogrel (Plavix)
      c. Dipyridamole
      d. Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
      e. Prasugrel (Effient)
      f. Ticagrelor (Brilinta)
      g. Ticlopidine
      h. Vorapaxar (Zontivity)

Effective: 07/01/26

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ROZANOLIXIZUMAB-NOLI

Generic	Brand				
ROZANOLIXIZUMAB-NOLI	RYSTIGGO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROZANOLIXIZUMAB-NOLI (Rystiggo)** requires the following rule(s) be met for approval:

- You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+) (a type of blood test that shows you have myasthenia gravis)
- You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
- You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
- You will NOT use Rystiggo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Imaavy [nipocalimab-aahu]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
  - You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

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ROZANOLIXIZUMAB-NOLI

RENEWAL CRITERIA

Our guideline named **ROZANOLIXIZUMAB-NOLI (Rystiggo)** requires the following rule(s) be met for renewal:

You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

You have had clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

You will NOT use Rystiggo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Imaavy [nipocalimab-aahu]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

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RUCAPARIB

Generic	Brand				
RUCAPARIB CAMSYLATE	RUBRACA				

GUIDELINES FOR USE

Our guideline named **RUCAPARIB (Rubraca)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that has returned)
- Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
- You are 18 years of age or older
- Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life)
- You are in complete or partial response to platinum-based chemotherapy (a type of therapy to treat cancer)

If you have metastatic castration-resistant prostate cancer, approval also requires:
- You are 18 years of age or older
- Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Rubraca
- You have been treated with an androgen receptor-directed therapy (type of therapy to treat cancer)
- You meet ONE of the following:
  - You previously received a bilateral orchiectomy (removal of both testicles)
  - You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
  - Rubraca will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

Effective: 01/19/26

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RUXOLITINIB

Generic	Brand				
RUXOLITINIB PHOSPHATE	JAKAFI , JAKAFI XR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RUXOLITINIB (Jakafi, Jakafi XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis (types of blood cancer)
   2. Polycythemia vera (a type of blood cancer)
   3. Steroid-refractory acute graft-versus-host disease (a type of short-term immune disorder that did not respond to a type of treatment)
   4. Chronic graft-versus-host disease (a type of long-term immune disorder)

B. **If you have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:**
   1. You are 18 years of age or older

C. **If you have polycythemia vera, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) hydroxyurea

D. **If you have steroid-refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older

E. **If you have chronic graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older
   2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
   3. You will NOT use the requested medication concurrently (at the same time) with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

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RUXOLITINIB

RENEWAL CRITERIA

NOTE: For the diagnoses of polycythemia vera, steroid-refractory acute graft-versus-host disease, or chronic graft-versus-host disease, please refer to the Initial Criteria section.

Our guideline named **RUXOLITINIB (Jakafi, Jakafi XR)** requires the following rule(s) be met for renewal:

A. You have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis (types of blood cancer)
B. You have shown symptom improvement by meeting ONE of the following:
    1. You have had at least a 50% reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
    2. You have had at least a 50% reduction in palpable (can be felt by external examination) spleen length
    3. You have had a spleen volume reduction of at least 35% from baseline (before treatment)

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RUXOLITINIB TOPICAL

Generic	Brand				
RUXOLITINIB PHOSPHATE	OPZELURA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. **If you have mild to moderate atopic dermatitis, approval also requires:**
   1. You are 2 years of age or older
   2. You are NOT immunocompromised (weak immune system)
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide)
      b. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical non-steroidal immunomodulating medication (such as Elidel [pimecrolimus], Protopic [tacrolimus])

C. **If you have nonsegmental vitiligo, approval also requires:**
   1. You are 12 years of age or older
   2. You have depigmented (lightening of the skin) areas covering 10% or less of your total body surface area (BSA)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) or a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
   4. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. **If you have mild to moderate atopic dermatitis, renewal also requires:**
   1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

C. **If you have nonsegmental vitiligo, renewal also requires:**
   1. You have experienced or maintained clinically meaningful repigmentation (recoloration of the skin after loss in color)
   2. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

Effective: 06/03/26

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SACITUZUMAB GOVITECAN-HZIY

Generic	Brand				
SACITUZUMAB GOVITECAN-HZIY	TRODELVY				

GUIDELINES FOR USE

Our guideline named **SACITUZUMAB GOVITECAN-HZIY (Trodelvy)** requires the following rule(s) be met for approval:

A. You have unresectable locally advanced or metastatic breast cancer (a type of breast cancer that cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. You meet ONE of the following:
    1. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); AND you are not a candidate for programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor based therapy (a type of cancer treatment)
    2. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); Trodelvy will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph); AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Combined Positive Score (CPS) of at least 10], as determined by a Food and Drug Administration (FDA)-authorized test
    3. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); AND you have tried two or more previous systemic therapies (treatment that targets the entire body such as docetaxel, paclitaxel), at least one of them for metastatic disease (disease that has spread to other parts of the body)
    4. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative (IHC 0, IHC 1+ or IHC 2+/ISH- [a type of lab test]); you have received endocrine (hormone)-based therapy (such as tamoxifen, Arimidex [anastrozole]); AND you have received at least two additional systemic therapies (treatment that targets the entire body such as Enhertu [fam-trastuzumab deruxtecan-nxki], Talzenna [talazoparib]) in the metastatic setting (disease has spread to other parts of the body)

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SACROSIDASE

Generic	Brand				
SACROSIDASE	SUCRAID				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:

A. You have sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
B. You are 5 months of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or medical geneticist (doctor who treats gene disorders)
D. You have tried to manage CSID (congenital sucrase-isomaltase deficiency: a type of genetic digestive condition) by keeping up with a sucrose-free/low sucrose diet (a type of diet)
E. You are experiencing symptoms, such as frequent watery diarrhea, abdominal pain/cramping, bloating, gas, dyspepsia (pain or discomfort in the stomach area), failure to thrive, weight loss, nausea and vomiting
F. You or your caregiver will keep up with any necessary diet restrictions while on Sucraid
G. Your diagnosis is confirmed by ONE of the following:
    1. Small bowel biopsy (removal of cells or tissue from the body for examination)
    2. Sucrose (a type of sugar) breath test
    3. Genetic test

RENEWAL CRITERIA

Our guideline named **SACROSIDASE (Sucraid)** requires the following rule(s) be met for renewal:

A. You have sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
B. You have experienced or maintained improvement on treatment

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SARGRAMOSTIM

Generic	Brand				
SARGRAMOSTIM	LEUKINE				

GUIDELINES FOR USE

Our guideline named **SARGRAMOSTIM (Leukine)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have undergone or are undergoing induction chemotherapy (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: type of blood cancer) AND you are 55 years of age or older
   3. You are undergoing autologous hematopoietic stem cell transplantation (a type of procedure to replace damaged bone marrow with your own health blood-forming cells) for cancer AND you are 18 years of age or older
   4. You have undergone or are undergoing autologous peripheral blood progenitor cell or bone marrow transplantation (procedures to get healthy blood-forming cells) for non-Hodgkin's lymphoma (NHL: a type of blood cancer), acute lymphoblastic leukemia (ALL: type of blood cancer), or Hodgkin's lymphoma (a type of blood cancer), AND you are 2 years of age or older
   5. You are undergoing allogeneic bone marrow transplantation from human leukocyte antigen (HLA: a type of protein)-matched related donor (a type of procedure to get healthy blood-forming cells) AND you are 2 years of age or older
   6. You have undergone allogeneic or autologous bone marrow transplantation (procedure to get healthy blood-forming cells), your neutrophil (a type of white blood cell) recovery is delayed or has failed, AND you are 2 years of age or older
   7. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS: an illness that happens after whole body radiation])

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SARILUMAB

Generic	Brand				
SARILUMAB	KEVZARA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polymyalgia rheumatica (PMR: an inflammatory disorder causing muscle pain and stiffness)
   3. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You meet ONE of the following:
      a. You have tried or have a contraindication to TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

b. You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. **If you have polymyalgia rheumatica, approval also requires:**
1. You are 18 years of age or older
2. You had an inadequate response (drug did not work) to corticosteroids (such as prednisone) or cannot tolerate a corticosteroid taper
3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polymyalgia rheumatica (an inflammatory disorder causing muscle pain and stiffness)

D. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
1. You weigh at least 63 kilograms (138 pounds)
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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SARILUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of polymyalgia rheumatica (PMR), please refer to the Initial Criteria section.

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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SARILUMAB

RENEWAL CRITERIA (CONTINUED)

C. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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SATRALIZUMAB-MWGE

Generic	Brand				
SATRALIZUMAB-MWGE	ENSPRYNG				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for approval:
You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
You have a positive serologic (blood) test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])
You have at least ONE of the following core clinical characteristics:
- Optic neuritis (a type of brain disorder)
- Acute myelitis (a type of brain disorder)
- Area postrema syndrome (a type of brain disorder)
- Acute brainstem syndrome (a type of brain disorder)
- Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

RENEWAL CRITERIA

Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for renewal:
You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
You have experienced a reduction in relapse frequency from baseline (before treatment)
You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

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SEBELIPASE ALFA (NSA)

Generic	Brand			
SEBELIPASE ALFA	KANUMA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for approval:

- You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol), as confirmed by the presence of clinical features such as hepatomegaly (enlarged liver), elevated serum transaminases (types of enzymes), dyslipidemia (abnormal levels of fats), splenomegaly (enlarge spleen)
- The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor), hepatologist (liver specialist), gastroenterologist (digestive system doctor), medical geneticist, or lipidologist (cholesterol management specialist)
- You meet ONE of the following:
  - A blood test indicating low or absent levels of lysosomal acid lipase enzyme activity
  - A dried blood spot test indicating low or absent lysosomal acid lipase enzyme activity
  - A genetic test indicating the bi-allelic presence of altered LIPA gene(s) (you have a change in a gene that provides instructions for producing an enzyme called lysosomal acid lipase)

RENEWAL CRITERIA

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for renewal:

- You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol) presenting after the first 6 months of life and not considered rapidly progressive (getting worse)
- You have documented improvement in ONE of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:
  - A relative reduction from baseline in any one of the following lipid levels (fat lab measurements such as LDL-c, Non-HDL-c, or triglycerides)
  - Normalization of aspartate aminotransferase (AST: type of liver enzyme) based on age- and gender-specific normal ranges
  - A decrease in liver fat content compared to baseline assessed by abdominal imaging such as multi-echo gradient echo [MEGE] MRI

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SEBETRALSTAT

Generic	Brand				
SEBETRALSTAT	EKTERLY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SEBETRALSTAT (Ekterly)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Ekterly will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Ekterly concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])
F. You meet ONE of the following:
    4. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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SEBETRALSTAT

RENEWAL CRITERIA

Our guideline named **SEBETRALSTAT (Ekterly)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use Ekterly concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

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SECUKINUMAB

Generic	Brand				
SECUKINUMAB	COSENTYX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   2. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
   3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

(Initial criteria continued on next page)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are 6 to 11 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast)
   b. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast), Icotyde (icotrokinra)
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Tremfya (guselkumab)
      iii. Skyrizi (risankizumab-rzaa)
      iv. Enbrel (etanercept)
      v. Otezla (apremilast)
      vi. Taltz (ixekizumab)
      vii. Sotyktu (deucravacitinib)
      viii. Bimzelx (bimekizumab-bkzx)
      ix. Adalimumab-ryvk/adalimumab-aaty
      x. Icotyde (icotrokinra)

C. **If you have psoriatic arthritis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Otezla (apremilast)
      iii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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INITIAL CRITERIA (CONTINUED)

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Taltz (ixekizumab)
   vii. Bimzelx (bimekizumab-bkzx)
   viii. Sotyktu (deucravacitinib)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Xeljanz IR/XR (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. **If you have ankylosing spondylitis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)

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INITIAL CRITERIA (CONTINUED)

4. You meet ONE of the following:
   a. You are 12 to 17 years of age
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Taltz (ixekizumab)
      iii. Bimzelx (bimekizumab-bkzx)
      iv. Adalimumab-ryvk/adalimumab-aaty
      v. Xeljanz IR/XR (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cimzia (certolizumab)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Cimzia])

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INITIAL CRITERIA (CONTINUED)

6. You have ONE of the following signs of inflammation:
   a. C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
   b. Sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

F. **If you have enthesitis-related arthritis, approval also requires:**
1. You are 4 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

G. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
1. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care therapy: topical therapy (such as clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (such as tetracycline, dapsone)
4. You meet ONE of the following:
   a. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Bimzelx (bimekizumab-bkzx)
      ii. Adalimumab-ryvk/adalimumab-aaty

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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SECUKINUMAB

RENEWAL CRITERIA

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You meet ONE of the following:
      a. You are 6 to 11 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast)
      b. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast), Icotyde (icotrokinra)

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RENEWAL CRITERIA (CONTINUED)

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications:
   i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   ii. Tremfya (guselkumab)
   iii. Skyrizi (risankizumab-rzaa)
   iv. Enbrel (etanercept)
   v. Otezla (apremilast)
   vi. Taltz (ixekizumab)
   vii. Sotyktu (deucravacitinib)
   viii. Bimzelx (bimekizumab-bkzx)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Icotyde (icotrokinra)

C. **If you have psoriatic arthritis, renewal also requires:**
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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RENEWAL CRITERIA (CONTINUED)

b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Otezla (apremilast)
   iii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Taltz (ixekizumab)
   vii. Bimzelx (bimekizumab-bkzx)
   viii. Sotyktu (deucravacitinib)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   3. You meet ONE of the following:
      a. You are 12 to 17 years of age
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Taltz (ixekizumab)
         iii. Bimzelx (bimekizumab-bkzx)
         iv. Adalimumab-ryvk/adalimumab-aaty
         v. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Cimzia (certolizumab)
      b. Taltz (ixekizumab)
      c. Bimzelx (bimekizumab-bkzx)
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Cimzia])

F. **If you have enthesitis-related arthritis, renewal also requires:**
   1. You have experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis (a type of joint condition)

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RENEWAL CRITERIA (CONTINUED)

G. **If you have moderate to severe hidradenitis suppurativa, renewal also requires:**
   1. You have shown improvement in your hidradenitis suppurativa symptoms
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)
   3. You meet ONE of the following:
      a. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
      b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
         i. Bimzelx (bimekizumab-bkzx)
         ii. Adalimumab-ryvk/adalimumab-aaty

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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SELADELPAR

Generic	Brand				
SELADELPAR LYSINE	LIVDELZI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), including cholestatic pruritus (itching caused by liver disease), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

D. You do NOT have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)

E. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) (Iqirvo [elafibranor]) or Lynavoy (linerixibat)

F. You meet ONE of the following:
   1. Livdelzi will be used as monotherapy (one medication treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Livdelzi will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one medication treatment)

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SELADELPAR

RENEWAL CRITERIA

Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for renewal:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) including cholestatic pruritus (itching caused by liver disease)
B. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) (Iqirvo [elafibranor]) or Lynavoy (linerixibat)
C. You meet ONE of the following:
    1. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67 times the upper limit of normal AND which has decreased by at least 15 percent from baseline (before treatment) while on treatment with Livdelzi
    2. You have cholestatic pruritus (itching caused by liver disease) associated with primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) AND have shown a clinical response, defined as improvement in pruritus (itching) symptoms

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SELEXIPAG

Generic	Brand				
SELEXIPAG	UPTRAVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. You meet ONE of the following:
    1. You are 2 to 17 years of age AND meet the following criterion:
        a. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
            i. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
            ii. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
            iii. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
    2. You are 18 years of age or older AND meet the following criterion:
        a. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
            i. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
            ii. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
            iii. Pulmonary vascular resistance (PVR) greater than 2 Wood units

RENEWAL CRITERIA

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 2 years of age or older

Effective: 08/08/26

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SELINEXOR

Generic	Brand				
SELINEXOR	XPOVIO				

GUIDELINES FOR USE

Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (MM: a type of blood cancer)
B. You are 18 years of age or older
C. You meet ONE of the following:
    1. Xpovio will be used in combination with bortezomib (Velcade) and dexamethasone; and you have received at least ONE prior therapy
    2. You have relapsed or refractory multiple myeloma (RRMM: a type of blood cancer that has returned or did not respond to treatment); Xpovio will be used in combination with dexamethasone; you have received at least four prior therapies for the treatment of RRMM; AND your disease is refractory (non-responsive) to ALL of the following:
        a. Two proteasome inhibitors (such as bortezomib [Velcade], carfilzomib [Kyprolis])
        b. Two immunomodulatory agents (such as lenalidomide [Revlimid], pomalidomide [Pomalyst])
        c. One anti-CD38 monoclonal antibody (such as daratumumab [Darzalex])

Effective: 06/03/26

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SELPERCATINIB

Generic	Brand				
SELPERCATINIB	RETEVMO				

GUIDELINES FOR USE

Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:
You have ONE of the following:

1. Locally advanced or metastatic non-small cell lung cancer (a type of lung cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
2. Advanced or metastatic medullary thyroid cancer (a type of thyroid cancer that has progressed or has spread to other parts of the body)
3. Advanced or metastatic thyroid cancer (thyroid cancer that has progressed or has spread to other parts of the body)
4. Locally advanced or metastatic solid tumors (abnormal mass that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)

If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:

1. You are 18 years of age or older
2. Your cancer has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

If you have advanced or metastatic medullary thyroid cancer, approval also requires:

1. You are 2 years of age or older
2. Your cancer has a rearranged during transfection (*RET*) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
3. You require systemic therapy (treatment that targets the entire body)

If you have advanced or metastatic thyroid cancer, approval also requires:

1. You are 2 years of age or older
2. Your cancer has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
3. You require systemic therapy (treatment that targets the entire body)
4. Your cancer is refractory (has not responded) to radioactive iodine therapy, if radioactive iodine is appropriate

If you have a locally advanced or metastatic solid tumors, approval also requires:

1. You are 2 years of age or older
2. Your tumor has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
3. Your tumor has progressed (worsened) on or following prior systemic treatment (treatment that targets the entire body) OR you have no alternative treatment options

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SELUMETINIB

Generic	Brand				
SELUMETINIB SULFATE	KOSELUGO				

GUIDELINES FOR USE

Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:
You have neurofibromatosis type 1 (NF1: a type of skin and nervous system disorder)
You are 1 year of age or older
You have symptomatic, inoperable (cannot be treated by surgery) plexiform neurofibromas (PN: tumors that grow along the nerves)

Effective: 12/15/25

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SEMAGLUTIDE - WEGOVY

Generic	Brand				
SEMAGLUTIDE	WEGOVY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. To reduce the risk of major adverse cardiovascular events (MACE: cardiovascular death, non-fatal myocardial infarction [heart attack], or non-fatal stroke [a type of brain damage])
   2. Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)/non-alcoholic steatohepatitis (NASH: a type of liver disease)
   3. Weight loss or weight management

B. **If you will use Wegovy to reduce the risk of major adverse cardiovascular events, approval also requires:**
   1. You are 18 years of age or older
   2. You are overweight as defined by ONE of the following:
      a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2)
      b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2)
   3. Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   4. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])

(Initial criteria continued on the next page)

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INITIAL CRITERIA (CONTINUED)

5. You have established cardiovascular disease as evidenced by ONE of the following:
   a. Prior myocardial infarction (heart attack)
   b. Prior stroke (ischemic [stroke caused by blood clot] or hemorrhagic [stroke caused by broken blood vessels in the brain])
   c. Carotid artery stenosis of at least 50 percent (the blood vessel that transports blood to the brain is blocked)
   d. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication (pain caused by too little blood flow) with ankle-brachial index (ABI: a type of test to check blood flow) less than 0.85 (at rest), peripheral arterial revascularization procedure (surgery to restore blood flow in blocked arteries/veins), or amputation due to atherosclerotic disease (buildup of fat)
6. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event:
   a. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (bleeding in the brain caused by broken blood vessels)
   b. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
   c. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

C. **If you will use Wegovy for noncirrhotic metabolic dysfunction-associated steatohepatitis/non-alcoholic steatohepatitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or endocrinologist (a type of hormone doctor)
   3. You are enrolled in or have already completed a lifestyle intervention (such as dietary, exercise, psychology)
   4. You will NOT use Wegovy concurrently (at the same time) with Rezdiffra (resmetirom), another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]), or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])

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INITIAL CRITERIA (CONTINUED)

5. You have had a biopsy (removal of cells or tissue from the body for examination) or non-invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) in the past 12 months which demonstrates liver fibrosis stage 2 or 3 (scoring system to measure liver damage)

D. **If you will use Wegovy for weight loss or weight management, approval also requires:**
   1. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   2. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   3. You meet ONE of the following:
      a. You are 18 years of age or older and meet ONE of the following before starting weight loss therapy:
         i. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
         ii. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
         iii. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

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INITIAL CRITERIA (CONTINUED)

iv. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

b. You are 12 to 17 years of age and meet the following:
   i. You have an initial body mass index (BMI: a tool for evaluating body fat) in the 95th percentile or greater standardized for your age and sex

RENEWAL CRITERIA

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. To reduce the risk of cardiovascular death, heart attack, and stroke (a type of brain damage)
   2. Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)/non-alcoholic steatohepatitis (NASH: a type of liver disease)
   3. Weight loss or weight management
B. **If you will use Wegovy to reduce the risk of cardiovascular death, heart attack, and stroke, renewal also requires:**
   1. You have cardiovascular disease (such as prior heart attack, prior stroke, carotid artery stenosis of at least 50 percent [the blood vessel that transports blood to the brain is blocked], symptomatic peripheral arterial disease [PAD])
   2. Wegovy will be used in combination with a reduced calorie diet and increased physical activity

(Renewal criteria continued on the next page)

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RENEWAL CRITERIA (CONTINUED)

3. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
4. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event (such as a non-fatal myocardial infarction [heart attack], non-fatal stroke [a type of brain damage]):
   a. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (a type of brain damage caused by broken blood vessels in the brain)
   b. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
   c. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

C. **If you will use Wegovy for noncirrhotic metabolic dysfunction-associated steatohepatitis/non-alcoholic steatohepatitis, renewal also requires:**
   1. Your disease is stable or has improved from baseline
   2. You will NOT use Wegovy concurrently (at the same time) with Rezdiffra (resmetirom), another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]), or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   3. You have had a biopsy (removal of cells or tissue from the body for examination) or non-invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) which demonstrates liver fibrosis stage 2 or 3 (scoring system to measure liver damage)

D. **If you will use Wegovy for weight loss or weight management, renewal also requires:**
   1. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])

(Renewal criteria continued on the next page)

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA (CONTINUED)

2. You meet ONE of the following:
    a. You are 12 to 17 years of age AND have achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat)
    b. You are 18 years of age or older and meet ALL of the following:
        i. You meet ONE of the following before starting weight loss therapy:
            1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
            2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
            3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
            4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
        ii. You have achieved or maintained at least a 5 percent weight loss of baseline body weight

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SEPIAPTERIN

Generic	Brand				
SEPIAPTERIN	SEPHIENCE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SEPIAPTERIN (Sephience)** requires the following rule(s) be met for approval:

You have sepiapterin-responsive phenylketonuria (PKU: a type of genetic metabolic disorder) with hyperphenylalaninemia (HPA: high levels of a type of amino acid)

You are 1 month of age or older

Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist (a doctor that treats metabolic or gene disorders)

You follow a phenylalanine-restricted diet (a type of diet)

You will NOT use Sephience concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])

You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kuvan (sapropterin)

RENEWAL CRITERIA

Our guideline named **SEPIAPTERIN (Sephience)** requires the following rule(s) be met for renewal:

You have sepiapterin-responsive phenylketonuria (PKU: a type of genetic metabolic disorder) with hyperphenylalaninemia (HPA: high levels of a type of amino acid)

Your phenylalanine (Phe) levels have decreased by at least 30 percent compared to baseline (before treatment) or to a level below 360 micromoles/L

You will NOT use Sephience concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])

Effective: 01/01/26

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SETMELANOTIDE

Generic	Brand				
SETMELANOTIDE ACETATE	IMCIVREE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Obesity (a condition where you have higher than normal body fat) due to Bardet-Biedl syndrome (BBS: a genetic disorder)
   2. Obesity (a condition where you have higher than normal body fat) due to pro-opiomelanocortin (POMC: type of protein), proprotein convertase subtilisin/kexin type 1 (PCSK1: type of protein), or leptin receptor (LEPR: type of protein) deficiency (low level), as determined by a Food and Drug Administration (FDA)-approved genetic test
   3. Acquired hypothalamic obesity (a condition where you have higher than normal body fat due to injury to the hypothalamus [a part of the brain])

B. **If you have obesity due to Bardet-Biedl syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or metabolic specialist (a doctor or health expert who focuses on how the body turns food into energy)
   2. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least in the 97th percentile for age, sex, and body weight
      b. You are 6 to 17 years of age AND have a baseline (before treatment) body weight of at least in the 97th percentile using growth chart assessments
      c. You are 18 years of age or older AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m2

(Initial criteria continued on next page)

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SETMELANOTIDE

INITIAL CRITERIA (CONTINUED)

C. **If you have obesity due to pro-opiomelanocortin, proprotein convertase subtilisin/kexin type 1, or leptin receptor deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or metabolic specialist (a doctor or health expert who focuses on how the body turns food into energy)
   2. You meet ONE of the following:
      a. You are 2 to 5 years of age AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least in the 97th percentile for age and sex
      b. You are 6 to 17 years of age AND have a baseline (before treatment) body weight of at least in the 95th percentile using growth chart assessments
      c. You are 18 years of age or older AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m2

D. **If you have acquired hypothalamic obesity, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or metabolic specialist (a doctor or health expert who focuses on how the body turns food into energy)
   2. You have or had hypothalamic damage or injury (damage or injury to part of the brain such as tumors impacting the hypothalamus [such as craniopharyngioma (a non-cancerous brain tumor)], surgery or radiation to treat those tumors, other forms of hypothalamic damage [such as brain injury impacting the region])
   3. You meet ONE of the following:
      a. You are 4 to 17 years of age AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least in the 95th percentile for age and sex on growth chart assessments
      b. You are 18 years of age or older AND have a baseline (before treatment) body mass index (BMI) of at least 30 kg/m2

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SETMELANOTIDE

RENEWAL CRITERIA

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Bardet-Biedl syndrome (BBS: a genetic disorder)
   2. Pro-opiomelanocortin (POMC: type of protein), proprotein convertase subtilisin/kexin type 1 (PCSK1: type of protein), or leptin receptor (LEPR: type of protein) deficiency (low level)
   3. Acquired hypothalamic obesity (HO: a condition where you have higher than normal body fat due to injury to the hypothalamus [a part of the brain])

B. You meet ONE of the following:
   1. You are 2 to 17 years of age AND have achieved or maintained at least a 5 percent weight loss of baseline (before treatment) body mass index (BMI: a tool for evaluating body fat)
   2. You are 18 years of age or older AND have achieved or maintained at least a 5 percent weight loss of baseline (before treatment) body weight

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Effective: 08/21/26

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SEVABERTINIB

Generic	Brand				
SEVABERTINIB	HYRNUO				

GUIDELINES FOR USE

Our guideline named **SEVABERTINIB (Hyrnuo)** requires the following rule(s) be met for approval:

You have locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body)

You are 18 years of age or older

Your tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

You have received a prior systemic therapy (such as cisplatin-based chemotherapy, carboplatin-based chemotherapy [types of therapy to treat cancer])

Effective: 12/22/25

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SIBEPRENLIMAB-SZSI

Generic	Brand				
SIBEPRENLIMAB-SZSI	VOYXACT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SIBEPRENLIMAB-SZSI (Voyxact)** requires the following rule(s) be met for approval:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You are 18 years of age or older
You are at risk for disease progression (worsening of disease)
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
Your diagnosis is confirmed by a biopsy (removal of cells or tissue from the kidney for examination)
You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Vanrafia (atrasentan), Filspari (sparsentan), Fabhalta (iptacopan)

RENEWAL CRITERIA

Our guideline named **SIBEPRENLIMAB-SZSI (Voyxact)** requires the following rule(s) be met for renewal:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You meet ONE of the following:
- You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
- You have improved or stable kidney function compared to baseline (before starting Voyxact)

Effective: 07/01/26

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SILDENAFIL IV

Generic	Brand				
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
E. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
F. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

RENEWAL CRITERIA

Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Effective: 07/01/24

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SILDENAFIL SUSPENSION

Generic	Brand				
SILDENAFIL CITRATE	REVATIO, LIQREV, SILDENAFIL CITRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. **If you are 1 to 17 years of age, approval also requires:**
    1. You are requesting Revatio (sildenafil) suspension
    2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
    3. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
        a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
        b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
        c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
    4. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
    5. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
    6. You are unable to swallow pills AND you have tried crushed sildenafil tablets

(Initial criteria continued on next page)

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

C. **If you are 18 years of age or older, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
   5. If you are requesting Revatio (sildenafil) suspension, you are unable to swallow pills AND you have tried crushed sildenafil tablets
   6. If you are requesting Liqrev suspension, you are unable to swallow Revatio (sildenafil) tablets AND you have tried the preferred medication: generic sildenafil powder for suspension

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. **If you are 1 to 17 years of age, approval also requires:**
   1. You are requesting Revatio (sildenafil) suspension
   2. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   3. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

C. **If you are 18 years of age or older, approval also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   2. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Effective: 06/03/26

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SILDENAFIL TABLET

Generic	Brand				
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. **If you are 1 to 17 years of age, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
C. **If you are 18 years of age or older, approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

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SILDENAFIL TABLET

RENEWAL CRITERIA

Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 1 year of age or older
C. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
D. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Effective: 07/01/24

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SILTUXIMAB (NSA)

Generic	Brand			
SILTUXIMAB	SYLVANT			

GUIDELINES FOR USE

Our guideline named **SILTUXIMAB (Sylvant)** requires the following rule(s) be met for approval:
You have multi-centric Castleman's disease (MCD: disease that affects the lymph nodes and related tissues)
You are negative for both human immunodeficiency virus (HIV) and human herpes virus-8 (HHV-8)

Effective: 07/01/20

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SIMVASTATIN 80

Generic	Brand				
EZETIMIBE/ SIMVASTATIN	VYTORIN				
SIMVASTATIN	ZOCOR, SIMVASTATIN				

GUIDELINES FOR USE

Our guideline named **SIMVASTATIN 80 (VYTORIN, ZOCOR)** requires the following rule(s) be met for approval:

A. You have been taking the medication for at least 12 months

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Effective: 05/14/21

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SIMVASTATIN ORAL SUSPENSION

Generic	Brand				
SIMVASTATIN	FLOLIPID				

GUIDELINES FOR USE

Our guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires the following rule(s) be met for approval:

You meet ONE of the following:

- You have a contraindication to (harmful for you to use) or are unable to swallow simvastatin oral tablets
- You have dysphagia (difficulty swallowing), difficulty swallowing tablets, or a feeding tube (such as a G-tube or J-tube)

Requests for zero-dollar cost share also requires the following:

- You are between 40 to 75 years old
- The requested quantity is within the low to moderate intensity daily dosage of 5mg to 40mg
- You are NOT concurrently (at the same time) taking any of the following secondary prevention medications for cardiovascular disease (heart disease):
  - Aspirin/dipyridamole (Aggrenox)
  - Clopidogrel (Plavix)
  - Dipyridamole
  - Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
  - Prasugrel (Effient)
  - Ticagrelor (Brilinta)
  - Ticlopidine
  - Vorapaxar (Zontivity)

Effective: 01/01/26

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SIPONIMOD

Generic	Brand				
SIPONIMOD	MAYZENT				

GUIDELINES FOR USE

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
You are 18 years of age or older
You have a CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype
You do NOT have any of the following contraindications to (harmful for you to use) Mayzent:
A CYP2C9*3/*3 genotype
Within the last 6 months, experienced a myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (TIA: short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
A presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, OR sick sinus syndrome, unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)

Effective: 01/01/26

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SIROLIMUS PROTEIN-BOUND (NSA)

Generic	Brand				
SIROLIMUS PROTEIN-BOUND	FYARRO				

GUIDELINES FOR USE

Our guideline named **SIROLIMUS PROTEIN-BOUND (Fyarro)** requires the following rule(s) be met for approval:

You have locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa: a type of rare tumor, that cannot be completely removed with surgery and has spread to nearby tissue or lymph nodes, or that has spread to other parts of the body)

You are 18 years of age or older

Effective: 04/01/22

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SIROLIMUS TOPICAL

Generic	Brand				
SIROLIMUS	HYFTOR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for approval:
You have facial angiofibroma (a type of skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)
You are 6 years of age or older

RENEWAL CRITERIA

Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for renewal:
A. You have facial angiofibroma (a type of skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)

Effective: 02/01/26

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SODIUM/CALCIUM/MAG/POT OXYBATE

Generic	Brand				
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Idiopathic hypersomnia (IH: a type of sleep disorder)
   2. Cataplexy in narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

B. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
   4. Your diagnosis is confirmed by ALL of the following:
      a. You do not have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing less than 2 sleep-onset REM sleep periods (SOREMP: time it takes to enter dream sleep) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   5. You tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred medications: armodafinil, modafinil

(Initial criteria continued on next page)

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

C. **If you have cataplexy in narcolepsy, approval also requires:**
   2. You are 7 years of age or older
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   4. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   5. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
      - A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
      - You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
      - You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   6. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
   7. You have tried TWO of the following preferred medications: venlafaxine, fluoxetine, tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

D. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for at least 3 months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
      d. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs: time it takes to enter dream sleep)
      e. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      f. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have normal levels of a chemical that helps with staying awake)
   5. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
   6. If you are 7 to 17 years old, you tried and failed or have a contraindication to (harmful for you to use) the following preferred medication: a generic stimulant (such as amphetamine, dextroamphetamine, methylphenidate)
   7. If you are 18 years or older, you tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. A generic typical stimulant (such as amphetamine sulfate, dextroamphetamine, methylphenidate)
      b. Armodafinil OR modafinil

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SODIUM/CALCIUM/MAG/POT OXYBATE

RENEWAL CRITERIA

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. **If you have narcolepsy, renewal also requires:**
   1. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
   2. You meet ONE of the following:
      a. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline (before treatment)
      b. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline
      c. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep)

C. **If you have idiopathic hypersomnia, renewal also requires:**
   1. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
   2. You meet ONE of the following:
      a. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline (before treatment)
      b. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline

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SODIUM OXYBATE-LUMRYZ

Generic	Brand				
SODIUM OXYBATE	LUMRYZ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

B. **If you have cataplexy with narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
      b. You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. You have tried the preferred medication: generic sodium oxybate
   6. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

C. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   4. You have excessive daytime sleepiness (EDS) persisting for at least 3 months
   5. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of greater than 10
   6. You have tried the preferred medication: generic sodium oxybate
   7. Your diagnosis is confirmed by ONE of the following:
      a. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND at least 2 early-onset rapid eye movement (REM) sleep test periods (SOREMPs: time it takes to enter dream sleep)
      b. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing an average sleep latency of 8 minutes or less AND at least one early-onset rapid eye movement (REM) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
      c. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have normal levels of a chemical that helps with staying awake)

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SODIUM OXYBATE-LUMRYZ

RENEWAL CRITERIA

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for renewal:

A. You have narcolepsy (a type of sleep condition)
B. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
C. You meet ONE of the following:
    1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
    2. You have maintained an improvement in Epworth Sleepiness Scale (ESS: tool to measure your sleepiness) scores by at least 25 percent compared to baseline
    3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep) compared to baseline

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SODIUM OXYBATE-XYREM

Generic	Brand				
SODIUM OXYBATE	XYREM, SODIUM OXYBATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:

E. You have ONE of the following:
   1. Idiopathic hypersomnia (IH: a type of sleep disorder)
   2. Cataplexy in narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

F. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), or Restoril (temazepam)
   4. You do NOT have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   5. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing less than 2 sleep-onset rapid eye movement (REM: a stage of sleep) sleep periods (SOREMP: time it takes to enter dream sleep), OR no SOREMPs if REM sleep latency (the time it takes to fall asleep and enter REM sleep stage) on a polysomnogram (type of sleep test) is 15 minutes or less
   6. You have one or more Multiple Sleep Latency Test (MSLT: a type of sleep study) mean (average) sleep latency (the time it takes to fall asleep) of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on a 24-hour polysomnography (type of sleep test) or by wrist actigraphy (device that monitors movement) in association with a sleep log
   7. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   8. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: armodafinil (Nuvigil), modafinil (Provigil)
   9. If you are requesting brand Xyrem, you have tried or have a contraindication to (harmful for you to use) generic sodium oxybate

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INITIAL CRITERIA (CONTINUED)

G. **If you have cataplexy in narcolepsy, approval also requires:**
   8. You are 7 years of age or older
   9. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   10. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   11. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
      b. You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   12. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Restoril (temazepam)
   13. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: venlafaxine, fluoxetine, a tricyclic anti-depressant (such as amitriptyline, clomipramine, imipramine)
   14. If you are requesting brand Xyrem, you have tried or have a contraindication to (harmful for you to use) generic sodium oxybate

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

H. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   8. You are 7 years of age or older
   9. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   10. You have excessive daytime sleepiness (EDS) persisting for at least 3 months
   11. You have an Epworth Sleepiness Scale (ESS: tool to measure sleepiness) score of more than 10
   12. You have ONE of the following:
      a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency (the time it takes to fall asleep) of 8 minutes or less AND at least 2 early-onset rapid eye movement (REM: a stage of sleep) sleep test periods (SOREMPs: time it takes to enter dream sleep)
      b. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing an average sleep latency (the time it takes to fall asleep) of 8 minutes or less AND at least one early-onset rapid eye movement (REM: a stage of sleep) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing normal levels of a chemical that helps with staying awake)
   13. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Restoril (temazepam)
   14. If you are 7 to 17 years old, you have tried or have a contraindication to (harmful for you to use) the following preferred medication: a generic stimulant (such as amphetamine sulfate, dextroamphetamine, or methylphenidate)
   15. If you are 18 years of age or older, you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications from EACH of the following categories:
      a. A generic typical stimulant (such as amphetamine sulfate, dextroamphetamine, methylphenidate)
      b. Armodafinil (Nuvigil) OR modafinil (Provigil)
   16. If you are requesting brand Xyrem, you have tried or have a contraindication to (harmful for you to use) generic sodium oxybate

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SODIUM OXYBATE-XYREM

RENEWAL CRITERIA

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:

D. You have ONE of the following:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

E. **If you have narcolepsy, renewal also requires:**
   3. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam]
   4. You meet ONE of the following:
      a. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline (before treatment)
      b. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline
      c. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep)

F. **If you have idiopathic hypersomnia, renewal also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam]
   2. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline (before treatment) OR you have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline

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SODIUM PHENYLBUTYRATE

Generic	Brand				
SODIUM PHENYLBUTYRATE	BUPHENYL, PHEBURANE, OLPRUVA, SODIUM PHENYLBUTYRATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for approval:

You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)

Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)

The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction

Your disorder cannot be managed by dietary protein restriction or amino acid supplementation alone

If your request is for Pheburane, approval also requires:

You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder

You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet

If your request is for Olpruva, approval also requires:

You are 1 year of age or older

You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder

You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet

RENEWAL CRITERIA

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for renewal:

You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)

You have experienced a clinical benefit from baseline (for example you have normal fasting glutamine levels, low-normal fasting ammonia levels, mental status clarity)

Effective: 02/11/26

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SOFOSBUVIR

Generic	Brand			
SOFOSBUVIR	SOVALDI			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You have genotype 2 or 3 infection (types of hepatitis C virus) and are 3 to 17 years of age OR you have genotype 1, 2, 3, or 4 infection (types of hepatitis C virus) and are 18 years of age or older
C. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
D. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
E. You will NOT use Sovaldi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin [rifapentine], St. John's wort, Aptivus [tipranavir]/ritonavir)
F. You will NOT use Sovaldi concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
G. **If you have genotype 2 infection, approval also requires:**
    1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
    2. Sovaldi will be used with ribavirin
    3. You meet ONE of the following:
        a. You are 3 to 17 years of age
        b. You are 18 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa
H. **If you have genotype 3 infection, approval also requires:**
    1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
    2. Sovaldi will be used with ribavirin
    3. You meet ONE of the following:
        a. You are 3 to 17 years of age
        b. You are 18 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) the preferred medication: Epclusa

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

I. **If you have genotype 1 infection, approval also requires:**
   1. You are 18 years of age or older
   2. You are treatment-naïve (no prior treatment)
   3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   4. Sovaldi will be used with peginterferon alfa and ribavirin OR Sovaldi will be used with ribavirin if you have a contraindication to (harmful for you to use) interferon
   5. You had an intolerance (side effect) or contraindication to ONE of the following preferred medications: Harvoni, Epclusa

J. **If you have genotype 4 infection, approval also requires:**
   1. You are 18 years of age or older
   2. You are treatment-naïve (no prior treatment)
   3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   4. Sovaldi will be used with peginterferon alfa and ribavirin
   5. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa

K. **If Sovaldi will be used to prevent post-transplant HCV reinfection (getting infected again with HCV after transplant), approval also requires:**
   1. You have hepatocellular carcinoma (HCC: a type of liver cancer)
   2. You are awaiting liver transplantation (you have not yet replaced your liver)
   3. Sovaldi will be used with ribavirin as pre-transplant (before transplant) treatment

L. **If you had a previous treatment failure with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir), approval also requires:**
   1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   2. Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

M. Sovaldi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Effective: 05/12/25

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SOFOSBUVIR/VELPATASVIR

Generic	Brand			
SOFOSBUVIR/ VELPATASVIR	EPCLUSA, SOFOSBUVIR/ VELPATASVIR			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 3 years of age or older
C. You have genotype 1, 2, 3, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You will NOT use Epclusa concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], efavirenz-containing HIV [human immunodeficiency virus] regimens, rosuvastatin at doses greater than 10mg, Aptivus [tipranavir]/ritonavir, topotecan, St. John's wort)
G. You will NOT use Epclusa concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

H. You meet ONE of the following:
   1. You do not have cirrhosis (liver damage and scarring)
   2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
   3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (moderate or severe liver impairment; Child-Pugh B or C [a score that evaluates the severity of liver damage]), and you meet ONE of the following:
      a. You will use Epclusa with ribavirin
      b. You have a contraindication to (harmful for you to use) ribavirin
      c. You have failed prior treatment with a sofosbuvir-based regimen (such as sofosbuvir/ribavirin) AND Epclusa will be used with ribavirin
      d. You have failed prior treatment with an NS5A inhibitor-based regimen (such as Harvoni [ledipasvir/sofosbuvir]) AND Epclusa will be used with ribavirin
      e. You received a liver transplant (replaced your liver), are treatment-experienced (failed prior treatment), AND Epclusa will be used with ribavirin

I. Epclusa will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand			
SOFOSBUVIR/VELPATASVIR/ VOXILAPREVIR	VOSEVI			

GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 18 years of age or older
C. You have genotype 1, 2, 3, 4, 5 or 6 infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Vosevi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, rifabutin, Priftin [rifapentine], rosuvastatin, pitavastatin, pravastatin at doses greater than 40mg, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, St. John's wort, HIV (human immunodeficiency virus) regimens containing atazanavir, lopinavir, Aptivus [tipranavir]/ritonavir, or efavirenz)
H. You will NOT use Vosevi concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
I. **If you are treatment-naïve (no prior treatment), approval also requires**:
    1. You have genotype 3 infection
    2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms)
    3. You have NS5A resistance-associated substitution (RAS) Y93H polymorphism (variations in a type of hepatitis C virus protein)

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GUIDELINES FOR USE (CONTINUED)

J. **If you are treatment-experienced (failed prior treatment), approval also requires**:
   1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   2. You meet ONE of the following:
      a. You have failed a full course of a regimen containing an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a direct-acting antiviral (such as Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant (replaced your liver or kidney)
      b. You have failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])
      c. You have failed prior treatment with Vosevi AND Vosevi will be used with ribavirin

K. Vosevi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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SOFPIRONIUM

Generic	Brand				
SOFPIRONIUM BROMIDE	SOFDRA				

GUIDELINES FOR USE

Our guideline named **SOFPIRONIUM (Sofdra)** requires the following rule(s) be met for approval:
You have primary axillary hyperhidrosis (excessive underarm sweating)
You are 9 years of age or older
You have primary axillary hyperhidrosis (excessive underarm sweating) as evidenced by focal (limited to a particular area of the body), visible, excessive sweating of at least 6 months duration with all secondary causes (caused by another medical condition) ruled out
You will NOT use Sofdra concurrently (at the same time) with other topical anticholinergics used for primary axillary hyperhidrosis (excessive underarm sweating) (such as Qbrexza [glycopyrronium tosylate])
You have at least two of the following:

1. Symptoms occur bilaterally (on both sides of the body)
2. Symptoms impair daily activities
3. You have at least one episode per week
4. Onset occurred before you turn(ed) 25 years old
5. You have a family history of primary axillary hyperhidrosis (excessive underarm sweating)
6. Symptoms do not occur during sleep

Effective: 08/01/26

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SOLIFENACIN SUSPENSION

Generic	Brand				
SOLIFENACIN SUCCINATE	VESICARE LS				

GUIDELINES FOR USE

Our guideline named **SOLIFENACIN SUSPENSION (Vesicare LS)** requires the following rule(s) be met for approval:
You have neurogenic detrusor overactivity (type of bladder condition)
You are 2 years of age or older
You have tried or have a contraindication to (harmful for you to use) TWO of the following:
- Anticholinergics (such as oxybutynin)
- Beta-3 agonists (such as Myrbetriq [mirabegron])

You are unable to swallow oral solifenacin tablets

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SOLRIAMFETOL

Generic	Brand				
SOLRIAMFETOL	SUNOSI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (a sleep condition with overwhelming daytime drowsiness)
   2. Excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) (a type of sleep condition due to a disorder where airflow is blocked during sleep)

B. **If you have excessive daytime sleepiness with narcolepsy, approval also requires:**
   1. Your diagnosis of narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
      a. You have had a sleep study (such as polysomnography [type of sleep test], multiple sleep latency test [MSLT: a type of sleep study])
      b. You have had a measurement of orexin levels (test showing you have low levels of a chemical that helps with staying awake)
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You have an Epworth Sleepiness Scale (ESS: tool to measure sleepiness) score of more than 10
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: a generic typical stimulant (such as amphetamine sulfate, methylphenidate), modafinil, armodafinil

(*Initial criteria continued on the next page)*

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INITIAL CRITERIA (CONTINUED)

C. **If you have excessive daytime sleepiness with obstructive sleep apnea, approval also require:**
   1. Your diagnosis of obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep) is confirmed by a polysomnography (a type of sleep test), home sleep apnea testing devices, or hospital-based bedside monitoring
   2. You have excessive daytime sleepiness with an Epworth Sleepiness Scale (ESS: tool to measure sleepiness) score of more than 10
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: modafinil, armodafinil
   4. You have been on a treatment for the obstructive causes of obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep), for at least one month since initiation

RENEWAL CRITERIA

Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (a sleep condition with overwhelming daytime drowsiness)
   2. Excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) (a type of sleep condition due to a disorder where airflow is blocked during sleep)
B. You have shown improvement in Epworth Sleepiness Scale (ESS: tool to measure sleepiness) scores by at least 25 percent compared to baseline (before treatment)

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SOMAPACITAN-BECO

Generic	Brand				
SOMAPACITAN-BECO	SOGROYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   3. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   4. You have growth failure associated with Noonan syndrome (a type of genetic disorder)

B. **If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:**
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
   4. You meet ONE of the following:
      a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
   5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

C. **If you are an adult patient with growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You meet ONE of the following:
      a. Your growth hormone deficiency is caused by a congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
      b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests (tests that measure the body's ability to produce growth hormone):
         i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
         ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
         iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
   4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

D. **If you have short stature born small for gestational age, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
   4. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
   5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

E. **If you have growth failure associated with Noonan syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
   3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
   4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

F. Request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

RENEWAL CRITERIA

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   3. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   4. You have growth failure associated with Noonan syndrome (a type of genetic disorder)

B. **If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal (before puberty) growth
   4. You meet ONE of the following:
      a. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
   5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

(Renewal criteria continued on next page)

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SOMAPACITAN-BECO

RENEWAL CRITERIA (CONTINUED)

C. **If you are an adult patient with growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)
   4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

D. **If you have short stature born small for gestational age OR growth failure associated with Noonan syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   2. Your epiphyses (end part of long bone) are not closed as confirmed by radiograph (a type of imaging test) of the wrist and hand OR you have not completed prepubertal (before puberty) growth
   3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty
   4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

E. Renewal request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROGON-GHLA

Generic	Brand				
SOMATROGON-GHLA	NGENLA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for approval:

- You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
- You are 3 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed, as confirmed by a radiograph (type of imaging test) of the wrist and hand
- You will NOT use Ngenla concurrently (at the same time) with Increlex (mecasermin)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Skytrofa (lonapegsomatropin-tcgd), Sogroya (somapacitan-beco)
- You meet ONE of the following:
  - Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
  - Your height velocity is less than the 25th percentile for your age
  - You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
- Request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROGON-GHLA

RENEWAL CRITERIA

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for renewal:

- You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
- You are 3 to 17 years of age
- Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
- Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
- You will NOT use Ngenla concurrently (at the same time) with Increlex (mecasermin)
- You meet ONE of the following:
  - Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
  - Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
- Renewal request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMATROPIN

Generic	Brand				
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, ZOMACTON				
	SAIZEN, SAIZEN-SAIZENPREP, SEROSTIM				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMATROPIN (Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen/Saizenprep, Serostim, Zomacton)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with wasting or cachexia (condition of severe weight and muscle loss)
   2. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   3. You have short stature associated with Noonan syndrome (a type of genetic disorder)
   4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (a type of genetic disorder)
   5. You have short stature associated with Turner syndrome (a type of genetic disorder)
   6. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   7. You have growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
   8. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)
   9. You have Prader-Willi syndrome (PWS: a type of genetic disorder)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

B. **If you have human immunodeficiency virus with wasting or cachexia, approval also requires:**
   1. You have NOT received a total of 48 weeks of cumulative treatment with any somatropin (such as Genotropin, Humatrope, Norditropin)
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist, or infectious disease specialist (a doctor who specializes in the treatment of infections)
   3. You are on optimized human immunodeficiency virus (HIV) anti-retroviral therapy (a type of treatment for an immune system disease caused by a virus)
   4. Alternative causes of wasting (such as altered metabolism [metabolic and hormonal abnormalities] including testosterone deficiency or peripheral growth hormone resistance, diarrhea, inadequate energy [caloric] intake, malignancies [tumors], or opportunistic infections [an infection that can occur because of a weakened immune system]) have been ruled out
   5. You meet ONE of the following:
      a. You have prolonged non-suppressed human immunodeficiency virus (HIV: an immune system disease caused by a virus) viremia (virus in the blood) (a viral load greater than 200 copies/mL) and meet ONE of the following:
         i. You have a greater than 10% loss of baseline body weight AND either chronic (long-term) diarrhea or chronic weakness or a fever for at least 30 days
         ii. You have 90% ideal body weight (or body mass index [BMI: a tool for evaluating body fat] of less than 18.5 kg/m[2]) AND a greater than 10% weight loss from premorbid maximum (highest weight before onset of disease) over a 12-month period
         iii. You have 90% ideal body weight (or body mass index [BMI: a tool for evaluating body fat] of less than 18.5 kg/m[2]) AND a greater than 5% weight loss in the previous 6 months
      b. You have suppressed human immunodeficiency virus (HIV: an immune system disease caused by a virus) viremia (virus in the blood) (a viral load less than 200 copies/mL) and meet ONE of the following:
         i. You have a greater than 5% loss of premorbid (before onset of disease) body weight over 6 months
         ii. You have a greater than 10% loss of premorbid (before onset of disease) body weight over 12 months
         iii. You have a low body mass index (BMI: a tool for evaluating body fat) (less than 20 kg/m[2]) if objective (measurable) weight loss is not available

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

C. **If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
   3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
   4. You meet at least ONE of the following:
      a. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) of at least 2 standard deviations below the mean for your age and gender
   5. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
      a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

D. **If you have short stature associated with Noonan syndrome OR short stature or growth failure with short stature homeobox-containing gene deficiency, approval also requires:**
   5. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   6. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
   7. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
   8. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
   9. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
      a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

E. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your Turner syndrome diagnosis was confirmed by chromosomal analysis (karyotyping: a type of genetic test)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
   4. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
   5. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
      a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

F. **If you have short stature born small for gestational age, approval also requires:**
   6. You are 2 years of age or older
   7. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   8. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
   9. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
   10. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
   11. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
      a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

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INITIAL CRITERIA (CONTINUED)

G. **If you have growth failure secondary to chronic kidney disease, approval also requires:**
   1. You are a pediatric patient
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor) or nephrologist (kidney doctor)
   3. You have not had a renal (kidney) transplant, or it has been at least one year since you had a renal (kidney) transplant
   4. You have persistent growth failure (height below the 10th percentile) and persistent low height velocity (below the 25th percentile)
   5. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
   6. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
      a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

H. **If you are an adult patient with growth hormone deficiency, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
   4. You meet ONE of the following:
      a. Your growth hormone deficiency is caused by a congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
      b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests (tests that measure the body's ability to produce growth hormone):
         i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
         ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
         iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

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INITIAL CRITERIA (CONTINUED)

5. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

I. **If you have Prader-Willi syndrome, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have a confirmed genetic diagnosis of Prader-Willi syndrome
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
4. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

J. Requests for Serostim will only be approved for human immunodeficiency virus with wasting or cachexia diagnosis

K. The requested medication will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (short height due to unknown cause)

RENEWAL CRITERIA

Our guideline named **SOMATROPIN (Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen/Saizenprep, Serostim, Zomacton)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
1. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with wasting or cachexia (condition of severe weight and muscle loss)
2. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
3. You have short stature associated with Noonan syndrome (a type of genetic disorder)
4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (a type of genetic disorder)
5. You have short stature associated with Turner syndrome (a type of genetic disorder)
6. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

7. You have growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
8. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)
9. You have Prader-Willi syndrome (PWS: a type of genetic disorder)

B. **If you have human immunodeficiency virus with wasting or cachexia, renewal also requires:**
   1. You have NOT received a total of 48 weeks of treatment with any somatropin (such as Genotropin, Humatrope, Norditropin)
   2. You are currently on optimized human immunodeficiency virus (HIV) anti-retroviral therapy (a type of treatment for an immune system disease caused by a virus)
   3. You have experienced a positive response to treatment (such as improvement in body mass index [BMI: a tool for evaluating body fat] or weight, physical improvements such as timed walk or chair rise)

C. **If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand OR you have not completed prepubertal growth)
   3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
   4. You meet ONE of the following:
      a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have short stature associated with Noonan syndrome, short stature or growth failure with short stature homeobox-containing gene deficiency, short stature associated with Turner syndrome, OR short stature born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are not closed as confirmed by radiograph (a type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
   3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR your annual growth velocity of at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty
   4. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

E. **If you have growth failure secondary to chronic kidney disease, renewal also requires:**
   1. You are a pediatric patient
   2. You have note not undergone a renal (kidney) transplantation within the past year
   3. You have a growth velocity of at least 2 cm compared with what was observed from the previous year OR annual growth velocity of at least 1 cm compared with what was observed from the previous year for patients that are near the terminal (end) phase of puberty
   4. Your epiphyses (end part of long bone) are not closed as confirmed by radiograph (a type of imaging test) of the wrist and hand, or you have not completed prepubertal growth
   5. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

F. **If you are an adult patient with growth hormone deficiency, renewal also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

G. **If you have Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have shown improvement in body composition
   3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

H. Requests for Serostim will only be approved for human immunodeficiency virus with wasting or cachexia diagnosis

I. The requested medication will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (short height due to unknown cause)

Effective: 07/01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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SOMATROPIN - ZORBTIVE

Generic	Brand				
SOMATROPIN	ZORBTIVE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOMATROPIN - ZORBTIVE** requires the following rule(s) be met for approval:

You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)

Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)

You are currently on specialized nutritional support (such as a high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)

Request for Zorbtive will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

RENEWAL CRITERIA

Our guideline named **SOMATROPIN - ZORBTIVE** requires the following rule(s) be met for renewal:

You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)

You have NOT been on the requested medication for a total of 4 weeks

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SONIDEGIB

Generic	Brand				
SONIDEGIB PHOSPHATE	ODOMZO				

GUIDELINES FOR USE

Our guideline named **SONIDEGIB (Odomzo)** requires the following rule(s) be met for approval:

A. You have locally advanced basal cell carcinoma (BCC: a type of skin cancer that has spread from where it started to nearby tissue or lymph nodes)
B. You are 18 years of age or older
C. This is a recurrence (disease returns) of basal cell carcinoma after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
D. You have obtained ALL of the following tests prior to starting therapy:
    1. Baseline serum creatine kinase (CK: a type of lab test) level
    2. Baseline serum creatinine level (a type of lab test to measure kidney function)
    3. If you are a female of reproductive potential, you have verified your pregnancy status

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SORAFENIB

Generic	Brand				
SORAFENIB TOSYLATE	NEXAVAR, SORAFENIB TOSYLATE				

GUIDELINES FOR USE

Our guideline named **SORAFENIB (Nexavar)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery)
   3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) (a type of thyroid cancer that returns, spreads, or is getting worse that does not fully respond to a type of treatment)

B. **If you have locally recurrent or metastatic, progressive, differentiated thyroid carcinoma, approval also requires:**
   1. Your cancer is refractory to radioactive iodine treatment (does not respond to a type of treatment)

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SOTATERCEPT-CSRK

Generic	Brand				
SOTATERCEPT-CSRK	WINREVAIR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age and older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    4. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    5. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    6. Pulmonary vascular resistance (PVR) greater than 2 Wood units
E. You meet ONE of the following:
    1. You have been on background PAH therapy (for at least 3 months) with at least TWO of the following medications from different drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
        d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])
    2. You are on ONE medication from one of the following drug classes, AND you have a contraindication to (harmful for you to use) or intolerance (side effect) to ALL of the other drug classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
        d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

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SOTATERCEPT-CSRK

RENEWAL CRITERIA

Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

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SOTORASIB

Generic	Brand				
SOTORASIB	LUMAKRAS				

GUIDELINES FOR USE

Our guideline named **SOTORASIB (Lumakras)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes, or has spread to other parts of the body)
   2. Metastatic colorectal cancer (mCRC: a type of digestive tract cancer that has spread to other parts of the body)

B. **If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
   3. You have received at least one prior systemic therapy (treatment that targets the entire body)

C. If you have metastatic colorectal cancer, approval also requires:
   1. You are 18 years of age or older
   2. Lumakras will be used in combination with Vectibix (panitumumab)
   3. Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
   4. You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (types of cancer treatments)

Effective: 02/24/25

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SPARSENTAN

Generic	Brand				
SPARSENTAN	FILSPARI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   2. Focal segmental glomerulosclerosis (FSGS: a type of kidney disease)

B. **If you have primary immunoglobulin A nephropathy, approval also requires:**
   1. You are 18 years of age or older
   2. You are at risk of disease progression (worsening)
   3. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   4. Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
   5. You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
   6. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
   7. You have tried or have a contraindication to (harmful for you to use) at least 12 weeks of treatment with ONE of the following clinical standard of care medications: an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)

C. **If you have focal segmental glomerulosclerosis, approval also requires:**
   1. You are 8 years of age or older
   2. You have proteinuria (high levels of protein in the urine)
   3. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   4. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
   5. You have a urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1.5 g/g
   6. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
   7. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE of the following clinical standard of care medications: an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril), an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)

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SPARSENTAN

INITIAL CRITERIA (CONTINUED)

8. You will NOT use Filspari concurrently (at the same time) with an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)
9. You do NOT have nephrotic syndrome (a type of kidney disease) as shown by nephrotic range proteinuria (high levels of protein in the urine) [urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of at least 3.0 g/g in adults (18 years of age or older); UPCR of at least 2.0 g/g in children (less than 18 years of age)]
10. You do NOT have nephrotic syndrome (a type of kidney disease) as shown by hypoalbuminemia (low levels of protein in the urine), edema (swelling caused by fluid build-up in the body), or hyperlipidemia (high level of fat in the blood)

RENEWAL CRITERIA

Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   2. Focal segmental glomerulosclerosis (FSGS: a type of kidney disease)

B. **If you have primary immunoglobulin A nephropathy, renewal also requires:**
   1. You have improved or stable kidney function compared to baseline (before starting Filspari) OR you have a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)

C. **If you have focal segmental glomerulosclerosis, renewal also requires:**
   1. You have had a greater than 40% reduction (decrease) in proteinuria (a condition with high levels of protein in the urine) compared to baseline (before starting Filspari)
   2. You have a urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of less than 1.5 g/g
   3. You will NOT use Filspari concurrently (at the same time) with an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)

Effective: 07/15/26

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SPESOLIMAB-SBZO - IV (NSA)

Generic	Brand				
SPESOLIMAB-SBZO	SPEVIGO				

GUIDELINES FOR USE

Our guideline named **SPESOLIMAB-SBZO - IV (Spevigo)** requires the following rule(s) be met for approval:

Spevigo will be used for the treatment of a generalized pustular psoriasis (GPP: a type of skin condition) flare

You are 12 years of age or older

You weigh at least 40 kilograms (88 pounds)

Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)

You have sterile, macroscopically visible pustules (blisters with non-infectious pus that can be seen with the naked eye) on non-acral skin (skin in areas of the body such as arms and legs)

You have NOT received more than one dose in the previous 30 days and that dose was NOT within the last 7 days

You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of generalized pustular psoriasis flare

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SPESOLIMAB-SBZO - SQ

Generic	Brand				
SPESOLIMAB-SBZO	SPEVIGO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for approval:

A. You have generalized pustular psoriasis (GPP: a type of skin condition)
B. You are 12 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
E. You have a history of generalized pustular psoriasis (GPP: a type of skin condition) flares of moderate to severe intensity defined as at least 5% body surface area (BSA) covered with erythema (a type of skin condition) and the presence of pustules (a type of skin condition) AND a Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA: a tool used to evaluate disease severity] total score of at least 3
F. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of generalized pustular psoriasis (GPP: a type of skin condition)

RENEWAL CRITERIA

Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for renewal:

A. You have generalized pustular psoriasis (GPP: a type of skin condition)
B. You have shown a clinical response to therapy
C. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of generalized pustular psoriasis (GPP: a type of skin condition)

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SPIRONOLACTONE

Generic	Brand				
SPIRONOLACTONE	CAROSPIR				

GUIDELINES FOR USE

Our guideline named **SPIRONOLACTONE (Carospir)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Heart failure (a type of heart condition)
- Hypertension (high blood pressure)
- Edema (swelling caused by fluid build-up in the body) caused by cirrhosis (liver damage and scarring)

If you have heart failure, approval also requires:
- You have New York Heart Association (NYHA) Class III-IV (a way to classify severity of heart failure symptoms)
- You have a reduced (lower) ejection fraction (amount of blood that the heart can pump out)
- You have a contraindication to (harmful for you to use) or are unable to swallow spironolactone tablets

If you have hypertension, approval also requires:
- Carospir will be used as add-on therapy
- You have a contraindication to (harmful for you to use) or are unable to swallow spironolactone tablets

If you have edema caused by cirrhosis, approval also requires:
- Your edema (swelling caused by fluid build-up in the body) has not responded to fluid and sodium restrictions (limiting the amount of liquids and sodium)
- You have a contraindication to (harmful for you to use) or are unable to swallow spironolactone tablets

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STIRIPENTOL

Generic	Brand				
STIRIPENTOL	DIACOMIT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:
You have seizures associated with Dravet syndrome (a rare type of seizure)
You are 6 months of age or older
You are currently being treated with clobazam (a type of seizure medication)
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
You have tried or have a contraindication to (harmful for you to use) valproic acid or derivatives

RENEWAL CRITERIA

Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:
You have seizures associated with Dravet syndrome (a rare type of seizure)
You are currently being treated with clobazam (a type of seizure medication)

Effective: 10/01/25

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SUFENTANIL (NSA)

Generic	Brand			
SUFENTANIL CITRATE	DSUVIA			

GUIDELINES FOR USE

Our guideline named **SUFENTANIL (Dsuvia)** requires the following rule(s) be met for approval:
You have acute pain (sudden and severe pain)
You are 18 years of age or older
Your pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate. Alternative treatments that may be inadequate include non-opioid analgesic products or opioid combination products
Your treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

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SULOPENEM ETZADROXIL-PROBENECID

Generic	Brand				
SULOPENEM ETZADROXIL-PROBENECID	ORLYNVAH				

GUIDELINES FOR USE

Our guideline named **SULOPENEM ETZADROXIL-PROBENECID (Orlynvah)** requires the following rule(s) be met for approval:

You have uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
You are a female AND 18 years of age or older
Your uncomplicated urinary tract infection (a type of bacterial infection) is caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* (types of bacteria)
You have limited or no alternative ORAL antibacterial treatment options
You meet ONE of the following:
- Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
- You have a documented culture demonstrating your uncomplicated urinary tract infection (a type of bacterial infection) is caused by a bacteria with sensitivity (lab test that shows what medications work on which bacteria) to sulopenem or ertapenem AND resistance (medication will not work for that bacteria) or contraindication (harmful for you to use) to all alternatives (such as Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [such as amoxicillin-clavulanate], cephalosporins [such as cephalexin], fluoroquinolones [such as ciprofloxacin])
- The request is for continuation of Orlynvah from an inpatient setting

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SUNITINIB

Generic	Brand			
SUNITINIB MALATE	SUTENT, SUNITINIB MALATE			

GUIDELINES FOR USE

Our guideline named **SUNITINIB (Sutent)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   2. Gastrointestinal stromal tumor (GIST: a type of digestive tumor)
   3. Unresectable locally advanced or metastatic pancreatic neuroendocrine tumor (pNET: a type of tumor in the pancreas that cannot be completely removed by surgery or has spread to other parts of the body)
   4. Renal cell carcinoma

B. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older

C. **If you have gastrointestinal stromal tumor, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) imatinib mesylate (Gleevec)

D. **If you have unresectable locally advanced or metastatic pancreatic neuroendocrine tumor, approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor is progressive (getting worse) and well-differentiated (looks like healthy cells)

E. **If you have renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as adjuvant (add-on) treatment
   3. You are at high risk of recurrent renal cell carcinoma (cancer returning) following nephrectomy (surgical removal of kidney)

Effective: 01/01/25

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SUTIMLIMAB-JOME (NSA)

Generic	Brand				
SUTIMLIMAB-JOME	ENJAYMO				

GUIDELINES FOR USE

Our guideline named **SUTIMLIMAB-JOME (Enjaymo)** requires the following rule(s) be met for approval:
You have cold agglutinin disease (CAD: a rare type of blood condition)
You are 18 years of age or older

Effective: 10/24/22

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SUZETRIGINE

Generic	Brand				
SUZETRIGINE	JOURNAVX				

GUIDELINES FOR USE

Our guideline named **SUZETRIGINE (Journavx)** requires the following rule(s) be met for approval:

A. You have moderate to severe acute (short-term) pain
B. You are 18 years of age or older
C. **If you have previously received treatment with Journavx, approval also requires:**
   1. The request is for the treatment of a new episode of acute pain

Effective: 07/01/25

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TADALAFIL

Generic	Brand				
TADALAFIL	CIALIS, TADALAFIL				

GUIDELINES FOR USE

Our guideline named **TADALAFIL (Cialis)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Benign prostatic hyperplasia (BPH: a type of prostate condition)
   2. Erectile dysfunction (difficulty getting or keeping an erection)

B. **If you have benign prostatic hyperplasia, approval also requires:**
   1. You have tried or have a contraindication to (harmful for you to use) ONE preferred formulary 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
   2. You have tried or have a contraindication to (harmful for you to use) ONE preferred formulary alpha blocker (such as doxazosin, terazosin, tamsulosin, alfuzosin)

C. **If you have erectile dysfunction, approval also requires**:
   1. You have tried the preferred medication: generic sildenafil (Viagra)

Effective: 06/03/26

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TADALAFIL-ADCIRCA, ALYQ

Generic	Brand				
TADALAFIL	ADCIRCA, ALYQ, TADALAFIL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for approval:

- You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension (a type of heart and lung condition) is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP: a type of measurement) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP: a type of measurement) of 15 mmHg or less
  - Pulmonary vascular resistance (PVR: a type of measurement) greater than 2 Wood units
- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

RENEWAL CRITERIA

Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for renewal:

- You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
- You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
- You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Effective: 01/01/26

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TAFAMIDIS

Generic	Brand			
TAFAMIDIS MEGLUMINE	VYNDAQEL			
TAFAMIDIS	VYNDAMAX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
D. You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
E. You will NOT use the requested medication concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)
F. Your diagnosis is confirmed by ONE of the following:
    1. A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)
    2. A biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

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TAFAMIDIS

RENEWAL CRITERIA

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:

A. You have cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You will NOT use the requested medication concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)

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TAFASITAMAB-CXIX

Generic	Brand				
TAFASITAMAB-CXIX	MONJUVI				

GUIDELINES FOR USE

Our guideline named **TAFASITAMAB-CXIX (Monjuvi)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Diffuse large B-cell lymphoma (DLBCL: a type of blood cancer)
- Follicular lymphoma (FL: a type of blood cancer)

If you have diffuse large B-cell lymphoma (not otherwise specified), approval also requires:

- You are 18 years of age or older
- Your cancer has relapsed or is refractory (cancer that has returned or does not fully respond to treatment)
- You are not eligible for autologous stem cell transplant (ASCT: stem cell transplant transferred from your own body)
- Monjuvi will be used in combination with Revlimid (lenalidomide)

If you have follicular lymphoma, approval also requires:

- You are 18 years of age or older
- Your cancer has relapsed or is refractory (cancer that has returned or does not fully respond to treatment)
- Monjuvi will be used in combination with Revlimid (lenalidomide) and rituximab

Effective: 08/11/25

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TAGRAXOFUSP-ERZS (NSA)

Generic	Brand			
TAGRAXOFUSP-ERZS	ELZONRIS			

GUIDELINES FOR USE

Our guideline named **TAGRAXOFUSP-ERZS (Elzonris)** requires the following rule(s) be met for approval:

You have blastic plasmacytoid dendritic cell neoplasm (BPDCN: aggressive and rare disease of the bone marrow and blood that can affect multiple organs)

You are 2 years of age or older

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TALAZOPARIB

Generic	Brand			
TALAZOPARIB TOSYLATE	TALZENNA			

GUIDELINES FOR USE

Our guideline named **TALAZOPARIB (TALZENNA)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic breast cancer (cancer that has spread to nearby tissue or lymph nodes or other parts of the body)
   2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have locally advanced or metastatic breast cancer, approval also requires:**
   1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   2. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (gBRCAm: a type of abnormal change in a gene), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic test for Talzenna
   3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
   4. You meet ONE of the following:
      a. You do NOT have hormone receptor (HR: a type of protein)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer, and you have been treated with prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]), or endocrine therapy is considered to be inappropriate for you

(Criteria continued on next page)

CONTINUE ON NEXT PAGE

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GUIDELINES FOR USE (CONTINUED)

C. **If you have prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Talzenna will be used in combination with Xtandi (enzalutamide)
   3. Your cancer has a homologous recombination repair (HRR) gene mutation (a type of abnormal change in a gene)
   4. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. Talzenna will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron-Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

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TALETRECTINIB

Generic	Brand				
TALETRECTINIB ADIPATE	IBTROZI				

GUIDELINES FOR USE

Our guideline named **TALETRECTINIB (Ibtrozi)** requires the following rule(s) be met for approval:

You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)

You are 18 years of age or older

Your tumor is ROS1-positive (abnormal change in a type of gene)

Effective: 08/04/25

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TALIGLUCERASE ALFA

Generic	Brand				
TALIGLUCERASE ALFA	ELELYSO				

GUIDELINES FOR USE

Our guideline named **TALIGLUCERASE ALFA (Elelyso)** requires the following rule(s) be met for approval:

You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)

You are 4 years of age or older

Effective: 02/09/26

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TALIMOGENE LAHERPAREPVEC (NSA)

Generic	Brand			
TALIMOGENE LAHERPAREPVEC	IMLYGIC			

GUIDELINES FOR USE

Our guideline for **TALIMOGENE LAHERPAREPVEC (Imlygic)** requires the following rule(s) be met for approval:

You have unresectable melanoma (type of skin cancer that cannot be removed with surgery)

Your melanoma lesions are recurrent after initial surgery (cancer returns after surgery)

You do not have a history of primary or acquired immunodeficient states (conditions that weaken your immune system), leukemia (type of white blood cell cancer), lymphoma (type of cancer affecting immune system), or Acquired Immunodeficiency Syndrome (AIDS)

You are not currently receiving immunosuppressive therapy (treatment that weakens your immune system)

You are not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy

The request is for Imlygic to be injected into cutaneous, subcutaneous, and/or nodal lesions (injected into the skin layers) that are visible, palpable (can be felt), or detectable by ultrasound guidance

Effective: 07/01/20

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TALQUETAMAB-TGVS (NSA)

Generic	Brand				
TALQUETAMAB-TGVS	TALVEY				

GUIDELINES FOR USE

Our guideline named **TALQUETAMAB-TGVS (Talvey)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
B. You are 18 years of age or older
C. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

Effective: 12/01/23

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TAPINAROF

Generic	Brand				
TAPINAROF	VTAMA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Plaque psoriasis (a type of skin condition)
   2. Atopic dermatitis (a type of skin condition)

B. **If you have plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications:
      i. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
      ii. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
      iii. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
      iv. Topical retinoid (such as tazarotene cream/gel)
      v. Anthralin

C. **If you have atopic dermatitis, approval also requires:**
   1. You are 2 years of age or older
   2. You meet ONE of the following:
      i. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
      ii. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

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TAPINAROF

RENEWAL CRITERIA

Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for renewal:

C. You have ONE of the following:
   1. Plaque psoriasis (a type of skin condition)
   2. Atopic dermatitis (a type of skin condition)

D. **If you have plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease

E. **If you have atopic dermatitis, renewal also requires:**
   1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

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Effective: 06/03/26

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TARLATAMAB-DLLE (NSA)

Generic	Brand				
TARLATAMAB-DLLE	IMDELLTRA				

GUIDELINES FOR USE

Our guideline named **TARLATAMAB-DLLE (Imdelltra)** requires the following rule(s) be met for approval:
You have small cell lung cancer (SCLC: a type of lung cancer)
You are 18 years of age or older
You have extensive-stage cancer (ES: cancer that has spread widely throughout the lungs or other parts of the body)
You have disease progression (worsening of disease) during or after platinum-based chemotherapy (a type of therapy to treat cancer such as carboplatin, cisplatin)

Effective: 06/10/24

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TASIMELTEON

Generic	Brand			
TASIMELTEON	HETLIOZ, HETLIOZ LQ, TASIMELTEON			

GUIDELINES FOR USE

Our guideline named **TASIMELTEON (Hetlioz, Hetlioz LQ)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD: a type of sleep condition)
   2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS: a type of developmental disorder that causes sleeping problems)

B. **If you have non-24 hour sleep-wake disorder, approval also requires:**
   1. You are 18 years of age or older
   2. You are light-insensitive (not affected by light) or have total blindness
   3. You have tried and failed maximally-tolerated melatonin therapy
   4. You are requesting the capsule

C. **If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:**
   1. You are requesting brand Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz LQ oral suspension if you are 3 to 15 years old
   3. You have tried and failed maximally-tolerated melatonin therapy

Effective: 01/01/25

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TAVABOROLE

Generic	Brand				
TAVABOROLE	KERYDIN, TAVABOROLE				

GUIDELINES FOR USE

Our guideline named **TAVABOROLE (Kerydin)** requires the following rule(s) be met for approval:
You have onychomycosis of the toenails (toenail fungus infection)
You meet ONE of the following:
- You have diabetes (a disorder with high blood sugar), peripheral vascular disease (PVD: a type of blood disorder), or a suppressed immune system
- You have pain surrounding the nail or soft tissue

You have tried or have a contraindication to (harmful for you to use) the following preferred medications:
- Oral terbinafine OR oral itraconazole
- Ciclopirox topical solution

Effective: 03/18/26

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TAZEMETOSTAT

Generic	Brand				
TAZEMETOSTAT	TAZVERIK				

GUIDELINES FOR USE

Our guideline named **TAZEMETOSTAT (Tazverik)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic or locally advanced epithelioid sarcoma (a type of soft tissue cancer that has spread to other parts of the body or has spread from where it started to nearby tissue or lymph nodes)
   2. Relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or did not respond to treatment)

B. **If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:**
   1. You are 16 years of age or older
   2. You are not eligible for complete resection (surgically removing all of a tissue/organ)

C. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years or older
   2. You meet ONE of the following:
      a. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (treatment that targets the entire body)
      b. You have no satisfactory alternative treatment options

Effective: 01/01/25

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TBO-FILGRASTIM

Generic	Brand				
TBO-FILGRASTIM	GRANIX				

GUIDELINES FOR USE

Our guideline named **TBO-FILGRASTIM (Granix)** requires the following rule(s) be met for approval:

A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
B. You are 1 month of age or older
C. Therapy is prescribed by or in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor)
D. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
E. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym

Effective: 11/01/22

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TEBENTAFUSP-TEBN (NSA)

Generic	Brand				
TEBENTAFUSP-TEBN	KIMMTRAK				

GUIDELINES FOR USE

Our guideline named **TEBENTAFUSP-TEBN (Kimmtrak)** requires the following rule(s) be met for approval:

You have unresectable or metastatic uveal melanoma (a type of eye cancer that is unable to be removed by surgery or has spread to other parts of the body)

You are 18 years of age or older

You are HLA-A*02:01-positive (a complex of genes)

Effective: 07/01/22

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TECLISTAMAB-CQYV

Generic	Brand				
TECLISTAMAB-CQYV	TECVAYLI				

GUIDELINES FOR USE

Our guideline named **TECLISTAMAB-CQYV (Tecvayli)** requires the following rule(s) be met for approval:

You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)

You are 18 years of age or older

You meet ONE of the following:

- You have received at least one prior line of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Tecvayli will be used in combination with Darzalex Faspro (daratumumab-hyaluronidase-fihj)
- You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

Effective: 03/18/26

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TEDIZOLID

Generic	Brand				
TEDIZOLID PHOSPHATE	SIVEXTRO				

GUIDELINES FOR USE

Our guideline named **TEDIZOLID (Sivextro)** requires the following rule(s) be met for approval:

A. You have an acute bacterial skin and skin structure infection (ABSSSI: a type of skin condition)
B. You meet ONE of the following:
   1. The request is for continuation of therapy of oral or intravenous (IV: injection into the vein) Sivextro
   2. You are being transitioned from IV Sivextro to oral Sivextro
   3. You had a trial of, contraindication to (harmful for you to use), or resistance to (medication no longer works as well) generic linezolid tablets
C. If your weight is between 1 kilogram to 34 kilograms (2.2 pounds to 74.8 pounds), only Sivextro intravenous vial will be approved

Effective: 05/12/25

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TEDUGLUTIDE

Generic	Brand			
TEDUGLUTIDE	GATTEX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for approval:

A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
B. You are 1 year of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
D. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

RENEWAL CRITERIA

Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for renewal:

A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
C. You have achieved at least a 20 percent reduction in parenteral support (administration of nutrition through a vein) compared to baseline
D. You have NOT achieved enteral autonomy (you still need nutrition through a tube)

Effective: 10/01/24

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TELISOTUZUMAB VEDOTIN-TLLV

Generic	Brand				
TELISOTUZUMAB VEDOTIN-TLLV	EMRELIS				

GUIDELINES FOR USE

Our guideline named **TELISOTUZUMAB VEDOTIN-TLLV (Emrelis)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body)
B. You are 18 years of age or older
C. Your tumor has high c-Met protein overexpression (at least 50 percent of tumor cells with strong [3+] staining) (too many proteins are made), as determined by a Food and Drug Administration (FDA)-approved test
D. You have received a prior systemic therapy (such as platinum therapy [a type of therapy to treat cancer])

Effective: 07/01/25

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TELOTRISTAT

Generic	Brand				
TELOTRISTAT ETIPRATE	XERMELO				

GUIDELINES FOR USE

Our guideline named **TELOTRISTAT (Xermelo)** requires the following rule(s) be met for approval:
You have carcinoid syndrome diarrhea (loose stools caused by a type of tumor)
You are 18 years of age or older
You will use Xermelo in combination with a somatostatin analog (SSA) (such as octreotide)
Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor) or gastroenterologist (doctor who treats digestive conditions)
You have been receiving a stable dose of long-acting somatostatin analog (SSA) therapy (such as Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) for at least 3 months
You have diarrhea that is inadequately controlled, as defined by having at least four bowel movements per day, while on somatostatin analog (SSA) therapy

Effective: 01/01/26

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TEMOZOLOMIDE

Generic	Brand				
TEMOZOLOMIDE	TEMODAR , TEMOZOLOMIDE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anaplastic astrocytoma (a type of brain cancer)
   2. Glioblastoma multiforme (a type of brain or spine cancer)
   3. Small cell lung cancer (SCLC: a type of lung cancer)
   4. Metastatic melanoma (a type of skin cancer that has spread to other parts of the body)

B. **If you have metastatic melanoma, approval also requires:**
   1. Temodar will NOT be used concurrently (at the same time) with an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

RENEWAL CRITERIA

NOTE: For the diagnoses of Anaplastic astrocytoma, Glioblastoma multiforme, or Small cell lung cancer (SCLC), please refer to the Initial Criteria section.

Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for renewal:

A. You have metastatic melanoma (a type of skin cancer that has spread to other parts of the body)
B. Temodar will NOT be used concurrently (at the same time) with an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

Effective: 01/01/25

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TEMSIROLIMUS (NSA)

Generic	Brand			
TEMSIROLIMUS	TORISEL			

GUIDELINES FOR USE

Our guideline named **TEMSIROLIMUS (Torisel)** requires the following rule(s) be met for approval:
You have advanced renal cell carcinoma (RCC: type of kidney cancer).

Effective: 07/01/20

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TENAPANOR

Generic	Brand				
TENAPANOR HCL	IBSRELA				

GUIDELINES FOR USE

Our guideline named **TENAPANOR (Ibsrela)** requires the following rule(s) be met for approval:

A. You have irritable bowel syndrome with constipation (IBS-C: a type of bowel disease)
B. You are 18 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) the preferred medications: Linzess (linaclotide) AND Trulance (plecanatide)

Effective: 01/01/25

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TEPLIZUMAB-MZWV

Generic	Brand				
TEPLIZUMAB-MZWV	TZIELD				

GUIDELINES FOR USE

TEPLIZUMAB-MZWV

GUIDELINES FOR USE (CONTINUED)

Our guideline named **TEPLIZUMAB-MZWV (Tzield)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Stage 2 type 1 diabetes (an immune disorder with high blood sugar)
   2. Stage 3 type 1 diabetes (an immune disorder with high blood sugar)

B. **If you have stage 2 type 1 diabetes, approval also requires:**
   1. You are 1 year of age or older
   2. You have at least two positive pancreatic islet autoantibodies (predictors of type 1 diabetes such as insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   3. An oral glucose tolerance test (or an alternative method, if oral glucose tolerance test is not available) confirms you have dysglycemia (abnormal blood sugar stability) without overt hyperglycemia (high blood sugar)
   4. Your clinical history does not suggest type 2 diabetes (a disorder with high blood sugar)
   5. You have NOT previously received a 14-dose treatment course

C. **If you have stage 3 type 1 diabetes, approval also requires:**
   1. You are 8 to 17 years of age
   2. You have been recently diagnosed (within the last 8 weeks)
   3. You have at least one positive pancreatic islet cell autoantibody (a predictor of type 1 diabetes such as insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   4. You have a peak C-peptide (a type of protein) of at least 0.2 pmol/mL on a mixed-meal tolerance test (a type of test that measures how the body regulates sugar levels in response to food) (or an alternative method, if a mixed-meal tolerance test is not available)

Effective: 07/15/26

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TEPOTINIB

Generic	Brand				
TEPOTINIB HCL	TEPMETKO				

GUIDELINES FOR USE

Our guideline named **TEPOTINIB (Tepmetko)** requires the following rule(s) be met for approval:

A. You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your tumors have mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a type of gene)

Effective: 01/01/25

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TEPROTUMUMAB-TRBW (NSA)

Generic	Brand				
TEPROTUMUMAB-TRBW	TEPEZZA				

GUIDELINES FOR USE

Our guideline named **TEPROTUMUMAB-TRBW (Tepezza)** requires the following rule(s) be met for approval:

You have thyroid eye disease (a rare condition where the muscles and fatty tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards)

Effective: 07/01/20

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TERAZOSIN

Generic	Brand				
TERAZOSIN HCL	TEZRULY				

GUIDELINES FOR USE

Our guideline named **TERAZOSIN (Tezruly)** requires the following rule(s) be met for approval:
You have ONE of the following:
Benign prostatic hyperplasia (BPH: a type of prostate condition)
Hypertension (high blood pressure)
If you have benign prostatic hyperplasia, approval also requires:
You have a contraindication to (harmful for you to use) or are unable to swallow terazosin capsules
If you have hypertension, approval also requires:
You have a contraindication to (harmful for you to use) or are unable to swallow terazosin capsules

Effective: 10/01/25

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TERIFLUNOMIDE

Generic	Brand			
TERIFLUNOMIDE	AUBAGIO, TERIFLUNOMIDE			

GUIDELINES FOR USE

Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Effective: 01/01/25

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TERIPARATIDE

Generic	Brand			
TERIPARATIDE	FORTEO, TERIPARATIDE			

GUIDELINES FOR USE

Our guideline named **TERIPARATIDE (Forteo)** requires the following rule(s) be met for approval:

- You have ONE of the following:
  - Postmenopausal osteoporosis (a type of bone condition)
  - Primary or hypogonadal (low level of sex hormones) osteoporosis (a type of bone condition) in a male patient
  - Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)
- You meet ONE of the following (1, 2, or 3):
  - You are at high risk for fractures defined as ONE of the following:
    - You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
    - You have TWO or more risk factors for a fracture (such as a history of multiple recent low trauma fractures, bone mineral density [BMD] T-score [a type of lab test] less than or equal to -2.5, corticosteroid [such as prednisone] use, or use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
    - You have had no prior treatment for osteoporosis, AND you have a Fracture Risk Assessment Tool (FRAX: a type of test) score of at least 20 percent for any major fracture OR at least 3 percent for a hip fracture
  - You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI: stomach and intestine) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine
  - You have tried, have an intolerance to (side effect), or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])
- You meet ONE of the following:
  - You have received a total of 24 months or more of treatment with Forteo (teriparatide) AND remain at or have returned to having a high risk for fracture
  - You have received a total of less than 24 months of treatment with Forteo (teriparatide)

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TESAMORELIN

Generic	Brand				
TESAMORELIN ACETATE	EGRIFTA SV, EGRIFTA WR				

GUIDELINES FOR USE

Our guideline named **TESAMORELIN (Egrifta SV, Egrifta WR)** requires the following rule(s) be met for approval:

You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with lipodystrophy (abnormal distribution of fat in the body)

You are 18 years of age or older

The requested medication will be used for the reduction of excess abdominal fat

You are currently receiving treatment with a protease inhibitor (PI: a type of medication), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI: a type of medication), OR an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

Effective: 08/11/25

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TESTOSTERONE

Generic	Brand				
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO, TESTOSTERONE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following showing you have low testosterone levels:
  - You have at least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
  - You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA
- If the request is for Androderm, Fortesta, Natesto, or Striant, you have tried or have a contraindication to (harmful for you to use) TWO preferred medications: testosterone cypionate and intramuscular (injected into the muscle) testosterone enanthate

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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TESTOSTERONE

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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TESTOSTERONE CYPIONATE - AZMIRO

Generic	Brand				
TESTOSTERONE CYPIONATE	AZMIRO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. You meet ONE of the following showing you have low testosterone levels:
      a. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      b. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic testosterone cypionate
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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TESTOSTERONE CYPIONATE - AZMIRO

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. **If you have gender dysphoria, renewal also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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Effective: 06/03/26

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TESTOSTERONE CYPIONATE - DEPO

Generic	Brand				
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE, TESTOSTERONE CYPIONATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following showing you have low testosterone levels:
  - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
  - You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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TESTOSTERONE CYPIONATE - DEPO

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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TESTOSTERONE ENANTHATE

Generic	Brand				
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Delayed puberty not due to a pathological disorder (disease) in a male
- Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, approval also requires:
- You meet ONE of the following showing you have low testosterone levels:
  - You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
  - You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA
- If the request is for Xyosted, approval also requires:
  - You are 18 years of age or older

If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

(Initial criteria continued on next page)

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

If you are a female with metastatic breast cancer, approval also requires:
- You meet ONE of the following:
  - You are postmenopausal (after menopause)
  - You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

If you have gender dysphoria, approval also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Delayed puberty not due to a pathological disorder (disease) in a male
- Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

If you are a male with primary or secondary hypogonadism, renewal also requires:
- You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
- You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
- If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
  - The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

(Renewal criteria continued on next page)

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA (CONTINUED)

If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
- You have NOT received more than two 6-month courses of testosterone replacement therapy
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

If you are a female with metastatic breast cancer, renewal also requires:
- You meet ONE of the following:
  - You are postmenopausal (after menopause)
  - You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
- The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

If you have gender dysphoria, renewal also requires:
- Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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TESTOSTERONE UNDECANOATE

Generic	Brand				
TESTOSTERONE UNDECANOATE	AVEED, JATENZO, KYZATREX, TLANDO, UNDECATREX				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TESTOSTERONE UNDECANOATE (Aveed, Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following showing you have low testosterone levels:
      a. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      b. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA
   4. If the request is for Aveed or Undecatrex, you have tried or have a contraindication to (harmful for you to use) TWO preferred generic medications (such as intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate, testosterone gel)
   5. If the request is for Jatenzo, Kyzatrex, or Tlando, you have tried or have a contraindication to (harmful for you to use) ONE preferred generic medication (such as intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate, testosterone gel)

(Initial criteria continued on next page)

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TESTOSTERONE UNDECANOATE

INITIAL CRITERIA (CONTINUED)

C. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

RENEWAL CRITERIA

Our guideline named **TESTOSTERONE UNDECANOATE (Aveed, Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. **If you have gender dysphoria, renewal also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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Effective: 08/01/26

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TETRABENAZINE

Generic	Brand				
TETRABENAZINE	XENAZINE, TETRABENAZINE				

GUIDELINES FOR USE

Our guideline named **TETRABENAZINE (Xenazine)** requires the following rule(s) be met for approval:

A. You have chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or movement disorder specialist
C. **If your request is for a tetrabenazine dose that is greater than 50 mg, approval also requires:**
    1. You have been genotyped (a type of lab test) for CYP2D6 (a type of enzyme) and you are identified as an extensive metabolizer (EM: normal enzyme activity) or intermediate metabolizer (IM: slower than normal enzyme activity) of CYP2D6

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TEZACAFTOR-IVACAFTOR

Generic	Brand			
TEZACAFTOR/IVACAFTOR	SYMDEKO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **TEZACAFTOR-IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You are homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) OR you have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Symdeko)

RENEWAL CRITERIA

Our guideline named **TEZACAFTOR-IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You have experienced an improvement in your clinical status
C. You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

Effective: 01/28/25

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TEZEPELUMAB-EKKO

Generic	Brand				
TEZEPELUMAB-EKKO	TEZSPIRE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Severe asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have severe asthma, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. Tezspire will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
   4. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   5. You meet ONE of the following:
      a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
      b. You have experienced at least ONE serious asthma exacerbation (worsening of symptoms) requiring a hospitalization or emergency room visit within the past 12 months
      c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
         i. Daytime asthma symptoms more than twice per week
         ii. Any night waking due to asthma
         iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         iv. Any activity limitation due to asthma

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   8. You are 12 years of age or older
   9. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   10. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
   11. You have inadequately controlled disease
   12. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
   13. Tezspire will be used as add-on maintenance treatment (in conjunction [together] with maintenance intranasal steroids [a type of medication used in the nose])
   14. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Severe asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have severe asthma, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
   2. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Tezspire)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in the percent predicted FEV1 (a type of lung test) from pretreatment baseline (before starting Tezspire)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   3. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)
   4. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

Effective: 06/03/26

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THALIDOMIDE

Generic	Brand				
THALIDOMIDE	THALOMID				

GUIDELINES FOR USE

Our guideline named **THALIDOMIDE (Thalomid)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Erythema nodosum leprosum (ENL: a type of immune condition)
   3. Anemia due to myelodysplastic syndrome (a type of blood condition due to blood cancer)
   4. Waldenström's macroglobulinemia (a type of blood cancer)

B. **If you have multiple myeloma, approval also requires:**
   1. Thalomid will be used in combination with dexamethasone

C. **If you have anemia due to myelodysplastic syndrome, approval also requires:**
   1. You have been treated for anemia due to myelodysplastic syndrome (a type of blood condition due to blood cancer)

Effective: 06/03/26

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THYROTROPIN ALFA (NSA)

Generic	Brand				
THYROTROPIN ALFA	THYROGEN				

GUIDELINES FOR USE

Our guideline named **THYROTROPIN ALFA (Thyrogen)** requires the following rule(s) be met for approval:

A. You have thyroid cancer
B. The requested medication will be used as adjunctive (add-on) treatment for radioiodine ablation of thyroid tissue remnants (used to destroy thyroid tissue that is left over after using another treatment)
C. You do not have metastatic disease (you have no signs of the disease spreading to other parts of the body)

NOTE: The requested medication is not covered under the pharmacy benefit when used as a diagnostic tool for serum thyroglobulin (Tg) testing. It may be covered under the medical benefit.

Effective: 11/14/22

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TILDRAKIZUMAB-ASMN

Generic	Brand				
TILDRAKIZUMAB-ASMN	ILUMYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
E. You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
F. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Tremfya (guselkumab)
    3. Skyrizi (risankizumab-rzaa)
    4. Enbrel (etanercept)
    5. Otezla (apremilast)
    6. Taltz (ixekizumab)
    7. Sotyktu (deucravacitinib)
    8. Bimzelx (bimekizumab-bkzx)
    9. Adalimumab-ryvk/adalimumab-aaty
    10. Icotyde (icotrokinra)

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INITIAL CRITERIA (CONTINUED)

G. You meet ONE of the following:
   1. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TILDRAKIZUMAB-ASMN

RENEWAL CRITERIA

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis [a type of skin condition]) of at least 50 percent or more
C. You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Tremfya (guselkumab)
    3. Skyrizi (risankizumab-rzaa)
    4. Enbrel (etanercept)
    5. Otezla (apremilast)
    6. Taltz (ixekizumab)
    7. Sotyktu (deucravacitinib)
    8. Bimzelx (bimekizumab-bkzx)
    9. Adalimumab-ryvk/adalimumab-aaty
    10. Icotyde (icotrokinra)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TIRZEPATIDE - ZEPBOUND

Generic	Brand				
TIRZEPATIDE	ZEPBOUND				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TIRZEPATIDE - ZEPBOUND** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Moderate to severe obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep)
   2. Weight loss or weight management

B. **If you will use Zepbound for moderate to severe obstructive sleep apnea, approval also requires:**
   1. You are 18 years of age or older
   2. You are obese as defined by ONE of the following:
      a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
      b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
   3. Your diagnosis is confirmed by documentation of an Apnea Hypopnea Index/Respiratory Disturbance Index/Respiratory Event Index (AHI/RDI/REI) of at least 15 events per hour that is predominantly obstructive
   4. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   5. You have persistent obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep) symptoms despite positive airway pressure (PAP: treatment method for sleep apnea) adherence (at least 4 hours per night on at least 70% of nights) OR there is clinical documentation that you are not a candidate for or are intolerant (side effect) to PAP
   6. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

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TIRZEPATIDE - ZEPBOUND

INITIAL CRITERIA (CONTINUED)

C. **If you will use Zepbound for weight loss or weight management, approval also requires:**
   1. You are 18 years of age or older
   2. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   3. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
   4. You meet ONE of the following before starting weight loss therapy:
      a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
      b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
      c. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
      d. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

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TIRZEPATIDE - ZEPBOUND

RENEWAL CRITERIA

Our guideline named **TIRZEPATIDE - ZEPBOUND** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Moderate to severe obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep)
   2. Weight loss or weight management

B. **If you will use Zepbound for moderate to severe obstructive sleep apnea, approval also requires:**
   1. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
   2. You have achieved or maintained a reduction in Apnea Hypopnea Index/Respiratory Disturbance Index/Respiratory Event Index (AHI/RDI/REI) by at least 15 events per hour or by at least 50%

C. **If you will use Zepbound for weight loss or weight management, approval also requires:**
   1. You meet ONE of the following before starting weight loss therapy:
   5. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
   6. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
   7. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

(Renewal criteria continued on next page)

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TIRZEPATIDE - ZEPBOUND

RENEWAL CRITERIA (CONTINUED)

8. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
2. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
3. You have achieved or maintained at least a 5% weight loss of baseline (before treatment) body weight

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Effective: 06/01/26

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TISOTUMAB VEDOTIN-TFTV (NSA)

Generic	Brand				
TISOTUMAB VEDOTIN-TFTV	TIVDAK				

GUIDELINES FOR USE

Our guideline named **TISOTUMAB VEDOTIN-TFTV (Tivdak)** requires the following rule(s) be met for approval:

You have recurrent or metastatic (cancer that has returned or spread to other parts of the body) cervical cancer

You are 18 years of age or older

You had disease progression on or after chemotherapy (drugs used to treat cancer)

Effective: 01/01/22

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TIVOZANIB

Generic	Brand				
TIVOZANIB HCL	FOTIVDA				

GUIDELINES FOR USE

Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory advanced renal cell carcinoma (a type of kidney cancer that returned or did not respond to treatment)
B. You are 18 years of age or older
C. You have received two or more systemic therapies (such as Cabometyx [cabozantinib], Keytruda [pembrolizumab], Opdivo [nivolumab])

Effective: 01/01/25

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TOBRAMYCIN INHALED

Generic	Brand				
TOBRAMYCIN	BETHKIS, TOBRAMYCIN				
TOBRAMYCIN IN 0.225% SOD CHLOR	TOBI, TOBRAMYCIN				
TOBRAMYCIN	TOBI PODHALER				
TOBRAMYCIN/NEBULIZER	KITABIS PAK, TOBRAMYCIN				

GUIDELINES FOR USE

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (a type of lung disoder)
B. You are 6 years of age or older
C. You have a lung infection with a gram-negative species (a type of bacteria such as Pseudomonas aeruginosa)
D. **If the request is for Tobi Podhaler, approval also requires ONE of the following:**
    1. You have tried or have a contraindication to (harmful for you to use) ONE generic inhaled tobramycin product
    2. You are not able to tolerate the prolonged administration of nebulizers

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TOCILIZUMAB - IV

Generic	Brand				
TOCILIZUMAB	ACTEMRA				

PAC NOTE: For requests for the SQ dosage form of Actemra, please see the TOCILIZUMAB-SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB - IV (Actemra - intravenous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   5. Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: a type of inflammatory response)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

5. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Rinvoq (upadacitinib)
      b. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

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INITIAL CRITERIA (CONTINUED)

D. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      v. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

E. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)

F. **If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome (a type of inflammatory response)

G. **NOTE:** Actemra will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized patients.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

Our guideline named **TOCILIZUMAB - IV (Actemra - intravenous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have giant cell arteritis, renewal also requires:**
   1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Rinvoq (upadacitinib)
      b. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

D. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      D. Enbrel (etanercept)
      E. Adalimumab-ryvk/adalimumab-aaty
      F. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      G. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      H. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

E. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
   3. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB - SQ

Generic	Brand				
TOCILIZUMAB	ACTEMRA				

PAC NOTE: For requests for the IV dosage form of Actemra, please see the TOCILIZUMAB - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

5. You have tried or have a contraindication to THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      E. Rinvoq (upadacitinib)
      F. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

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INITIAL CRITERIA (CONTINUED)

D. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD: acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
   5. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

F. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have giant cell arteritis, renewal also requires:**
   1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Rinvoq (upadacitinib)
      b. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

D. **If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

E. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

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RENEWAL CRITERIA (CONTINUED)

3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

F. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   2. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
   3. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-AAZG - IV

Generic	Brand				
TOCILIZUMAB-AAZG	TYENNE				

PAC NOTE: For requests for the SQ dosage form of Tyenne, please see the TOCILIZUMAB-AAZG-SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB-AAZG - IV (Tyenne - intravenous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   5. Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: a type of inflammatory response)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INITIAL CRITERIA (CONTINUED)

5. You have tried or have a contraindication to ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

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INITIAL CRITERIA (CONTINUED)

4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)

F. **If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome (a type of inflammatory response)

G. **NOTE:** Tyenne will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized patients.

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

Our guideline named **TOCILIZUMAB-AAZG - IV (Tyenne - intravenous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. **If you have giant cell arteritis, renewal also requires:**
   1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Renewal criteria continued on next page)

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA (CONTINUED)

D. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   2. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

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TOCILIZUMAB-AAZG - SQ

Generic	Brand				
TOCILIZUMAB-AAZG	TYENNE				

PAC NOTE: For requests for the IV dosage form of Tyenne, please see the TOCILIZUMAB-AAZG - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD: acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
   5. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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INITIAL CRITERIA (CONTINUED)

E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

F. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. **If you have giant cell arteritis, renewal also requires:**
   1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

E. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

F. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   2. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

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RENEWAL CRITERIA (CONTINUED)

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TOCILIZUMAB-ANOH - SQ

Generic	Brand				
TOCILIZUMAB-ANOH	AVTOZMA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB-ANOH - SQ (Avtozma - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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TOCILIZUMAB-ANOH - SQ

INITIAL CRITERIA (CONTINUED)

C. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
   3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD: acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
   5. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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INITIAL CRITERIA (CONTINUED)

E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

F. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-ANOH - SQ

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB-ANOH - SQ (Avtozma - subcutaneous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. **If you have giant cell arteritis, renewal also requires:**
   1. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. **If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
   2. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

E. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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TOCILIZUMAB-ANOH - SQ

RENEWAL CRITERIA (CONTINUED)

F. **If you have systemic juvenile idiopathic arthritis, renewal also requires:**
   1. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
   2. You meet ONE of the following:
      a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Effective: 07/01/26

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TOFACITINIB

Generic	Brand				
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR, TOFACITINIB CITRATE, TOFACITINIB CITRATE ER				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Enbrel [etanercept])

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam, diclofenac)
   5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty)

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INITIAL CRITERIA (CONTINUED)

F. **If you have polyarticular course juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis (a type of joint condition)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

RENEWAL CRITERIA

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   6. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   7. Psoriatic arthritis (PsA: a type of skin and joint condition)
   8. Ankylosing spondylitis (AS: a type of joint condition)
   9. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   10. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

(Renewal criteria continued on next page)

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have ankylosing spondylitis, renewal also requires**:
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

F. **If you have polyarticular course juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis (a type of joint condition)

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TOFERSEN (NSA)

Generic	Brand				
TOFERSEN	QALSODY				

GUIDELINES FOR USE

Our guideline named **TOFERSEN (QALSODY)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
D. You have a superoxide dismutase 1 (SOD1: an enzyme) gene mutation (an abnormal change in your gene)

Effective: 08/28/23

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TOLVAPTAN

Generic	Brand			
TOLVAPTAN	JYNARQUE			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:

A. You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
D. You do NOT have end-stage renal disease (ESRD: advanced kidney disease), including no renal transplantation (kidney transplant) or dialysis (process of removing excess water, toxins from the blood)

RENEWAL CRITERIA

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:

A. You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
B. You have NOT progressed to end stage renal disease (ESRD: advanced kidney disease)

Effective: 07/01/25

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TOPIRAMATE

Generic	Brand				
TOPIRAMATE	EPRONTIA, TOPIRAMATE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOPIRAMATE (Eprontia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic seizures (a type of seizure)
   3. Seizures associated with Lennox-Gastaut syndrome (a type of seizure disorder in young children)
   4. Migraine (a type of headache)

B. **If you have partial-onset seizures or primary generalized tonic-clonic seizures, approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication will be used as initial monotherapy (one medication treatment) OR adjunctive therapy (medications taken together with)
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   4. You have a contraindication to (harmful for you to use) or are unable to swallow oral topiramate tablets or capsules
   5. You have tried or have a contraindication to (harmful for you to use) THREE preferred anti-seizure medications (such as carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate tablets or capsules, lamotrigine)

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TOPIRAMATE

INITIAL CRITERIA (CONTINUED)

C. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication will be used as adjunctive therapy (medications taken together with)
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   4. You have a contraindication to (harmful for you to use) or are unable to swallow oral topiramate tablets or capsules
   5. You have tried or have a contraindication to (harmful for you to use) the standard of care medication: valproic acid or derivatives
   6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred anti-seizure medications: Epidiolex, rufinamide, felbamate, clobazam, lamotrigine, clonazepam, generic topiramate tablets or capsules

D. **If you have migraines, approval also requires:**
   1. You are 12 years of age or older
   2. The requested medication will be used as preventative treatment of migraines
   3. You are unable to take oral tablets or capsules
   4. You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: Trokendi XR, generic topiramate tablet/sprinkle, topiramate extended release (ER) sprinkle

RENEWAL CRITERIA

NOTE: For the diagnosis of migraines, please refer to the Initial Criteria section.

Our guideline named **TOPIRAMATE (Eprontia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic seizures (a type of seizure)
   3. Seizures associated with Lennox-Gastaut syndrome (a type of seizure disorder in young children)

Effective: 06/03/26

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TOREMIFENE

Generic	Brand			
TOREMIFENE CITRATE	FARESTON, TOREMIFENE CITRATE			

GUIDELINES FOR USE

Our guideline named **TOREMIFENE (Fareston)** requires the following rule(s) be met for approval:

A. You have metastatic breast cancer (cancer that has spread to other parts of the body)
B. You are a postmenopausal female (after menopause)
C. You have estrogen-receptor positive or unknown tumors

Effective: 05/05/25

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TORIPALIMAB-TPZI (NSA)

Generic	Brand				
TORIPALIMAB-TPZI	LOQTORZI				

GUIDELINES FOR USE

Our guideline named **TORIPALIMAB-TPZI (Loqtorzi)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Metastatic or recurrent locally advanced nasopharyngeal carcinoma (a type of neck cancer that has spread to other parts of the body or was previously treated and has spread to nearby tissue or lymph nodes)
- Recurrent unresectable or metastatic nasopharyngeal carcinoma (a type of neck cancer that was previously treated and unable to be removed by surgery or that has spread to other parts of the body)

If you have metastatic or recurrent locally advanced nasopharyngeal carcinoma, approval also requires:

- You are 18 years of age or older
- Loqtorzi is for first-line treatment
- Loqtorzi will be used in combination with cisplatin and gemcitabine

If you have recurrent unresectable or metastatic nasopharyngeal carcinoma, approval also requires:

- You are 18 years of age or older
- Loqtorzi will be used as a single agent
- You have experienced disease progression on or after a platinum-containing chemotherapy (such as cisplatin)

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TOVORAFENIB

Generic	Brand				
TOVORAFENIB	OJEMDA				

GUIDELINES FOR USE

Our guideline named **TOVORAFENIB (Ojemda)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory low-grade glioma (LGG) (a type of brain cancer that has returned or did not respond to treatment)
B. Your cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation (types of abnormal changes in genes)

Effective: 06/10/24

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TRABECTEDIN (NSA)

Generic	Brand			
TRABECTEDIN	YONDELIS			

GUIDELINES FOR USE

Our guideline named **TRABECTEDIN (Yondelis)** requires the following rule(s) be met for approval:

You have unresectable or metastatic liposarcoma or leiomyosarcoma (cancer of the fat cells or muscles that cannot be removed with surgery or has spread to other parts of body).

You have previously received therapy with an anthracycline-containing regimen such as doxorubicin.

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TRALOKINUMAB-LDRM

Generic	Brand				
TRALOKINUMAB-LDRM	ADBRY				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
E. You meet ONE of the following:
    1. You were previously stable on another biologic (such as Dupixent [dupilumab], Rinvoq [upadacitinib]) and are switching to Adbry
    2. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
    3. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies:
    1. Topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate)
    2. Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
    3. Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
    4. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
    5. Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
    6. Phototherapy (a type of light therapy)

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TRALOKINUMAB-LDRM

RENEWAL CRITERIA

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for renewal:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You have shown improvement while on Adbry
C. You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

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TRAMADOL

Generic	Brand				
TRAMADOL HCL	QDOLO, TRAMADOL HCL				

GUIDELINES FOR USE

Our guideline named **TRAMADOL (Qdolo)** requires the following rule(s) be met for approval:
The request is for the management of pain
You are 18 years of age or older
Your pain is severe enough to require an opioid analgesic (type of pain medication)
Alternative (other) treatments for your pain are inadequate (did not work)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic tramadol immediate-release (IR) tablet or a generic tramadol with acetaminophen product
You are unable to take oral solid formulations (such as a tablet) of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

Effective: 03/04/26

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TRAMETINIB

Generic	Brand			
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST			

GUIDELINES FOR USE

Our guideline named **TRAMETINIB (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread to nearby tissue or lymph nodes or has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used in combination with Tafinlar (dabrafenib)

D. **If you have melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used as an adjuvant (add-on) therapy in combination with Tafinlar (dabrafenib)
   3. There is involvement of lymph node(s), following complete resection (surgical removal)

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have a BRAF V600E mutation (abnormal change in gene)
   2. Mekinist will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

F. **If you have an unresectable or metastatic solid tumor, approval also requires:**
   1. You are 1 year of age or older
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. Mekinist will be used in combination with Tafinlar (dabrafenib)
   4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. **If you have low-grade glioma, approval also requires:**
   1. You are 1 to 17 years of age
   2. You have a BRAF V600E mutation (abnormal change in gene)
   3. Mekinist will be used in combination with Tafinlar (dabrafenib)
   4. You require systemic therapy (treatment that targets the entire body)

H. **If the request is for the oral solution, approval also requires:**
   1. You are unable to swallow Mekinist (trametinib) tablets

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TRASTUZUMAB-ANNS (NSA)

Generic	Brand			
TRASTUZUMAB-ANNS	KANJINTI			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-ANNS (Kanjinti)** requires the following rule(s) be met for approval:

You have **ONE** of the following diagnoses:
- Breast cancer
- Metastatic breast cancer (breast cancer that has spread to other parts of body)
- Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

If you have breast cancer, approval also requires:
- You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
- The request is for adjuvant (add-on) therapy
- You meet **ONE** of the following:
  - The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
  - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

If you have metastatic breast cancer, approval also requires:
- You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
- You meet **ONE** of the following:
  - The requested medication is being used in combination with paclitaxel for first-line treatment
  - The requested medication is being used as a single agent if you have previously received **ONE** or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB-ANNS (NSA)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body), approval also requires:

You have HER2-positive tumor (you have a type of protein present in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test

The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil

You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB-DKST (NSA)

Generic	Brand			
TRASTUZUMAB-DKST	OGIVRI			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-DKST (Ogivri)** requires the following rule(s) be met for approval:

You have **ONE** of the following diagnoses:
- Breast cancer
- Metastatic breast cancer (cancer has spread to other parts of the body)
- Metastatic gastric or gastroesophageal junction adenocarcinoma (type of cancer in the stomach and/or lower throat that has spread to other parts of the body)

If you have breast cancer, approval also requires:
- You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
- The request is for adjuvant (add-on) therapy
- You meet **ONE** of the following:
  - The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
  - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

If you have metastatic breast cancer, approval also requires:
- You have HER2-positive metastatic breast cancer (you have a type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
- You meet **ONE** of the following:
  - The requested medication is being used in combination with paclitaxel for first-line treatment
  - The requested medication is being used as a single agent if you have previously received **ONE** or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
- You have HER2-positive metastatic cancer (you have a type of protein and the cancer has spread to other parts of the body) as detected by a Food and Drug Administration-(FDA)-approved test
- The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
- You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB-DTTB (NSA)

Generic	Brand				
TRASTUZUMAB-DTTB	ONTRUZANT				

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB- DTTB (Ontruzant)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:
- Breast cancer
- Metastatic breast cancer (breast cancer that has spread to other parts of the body)
- Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

If you have breast cancer, approval also requires:
- The request is for adjuvant (add-on) therapy
- You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
- You meet ONE of the following:
  - The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
  - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
- You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

If you have metastatic breast cancer, approval also requires:
- You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
- You meet ONE of the following:
  - The requested medication is being used in combination with paclitaxel for first-line treatment
  - The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
- You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

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TRASTUZUMAB-DTTB (NSA)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

- You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
- The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
- You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB-PKRB (NSA)

Generic	Brand				
TRASTUZUMAB-PKRB	HERZUMA				

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-PKRB (Herzuma)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:
- Breast cancer
- Metastatic breast cancer (breast cancer that has spread to other parts of the body)
- Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

If you have breast cancer, approval also requires:
- You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
- The request is for adjuvant (add-on) treatment
- You meet ONE of the following:
  - The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
  - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
- You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

If you have metastatic breast cancer, approval also requires:
- You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
- You meet ONE of the following:
  - The requested medication is being used in combination with paclitaxel for first-line treatment
  - The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
- You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

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TRASTUZUMAB-PKRB (NSA)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

You have HER2-positive tumor (type of protein found in stomach cancer) as detected by a Food and Drug Administration (FDA)-approved test

The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil

You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB-QYYP (NSA)

Generic	Brand			
TRASTUZUMAB-QYYP	TRAZIMERA			

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB- QYYP (Trazimera)** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:
- Breast cancer
- Metastatic breast cancer (breast cancer that has spread to other parts of the body)
- etastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

If you have breast cancer, approval also requires:
- The request is for adjuvant (add-on) therapy
- You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
- You meet ONE of the following:
  - The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
  - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

If you have metastatic breast cancer, approval also requires:
- You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
- You meet ONE of the following:
  - The requested medication is being used in combination with paclitaxel for first-line treatment
  - The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB-QYYP (NSA)

GUIDELINES FOR USE (CONTINUED)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

- You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
- The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
- You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

Generic	Brand				
TRASTUZUMAB	HERCEPTIN				
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA				

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (Herceptin, Herceptin Hylecta)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for trastuzumab
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Ogivri (trastuzumab-dkst)
   3. You meet ONE of the following:
      a. The requested medication will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. The requested medication will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. The requested medication will be used as part of a treatment plan with docetaxel and carboplatin
         iii. The requested medication will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
         i. The requested medication will be used in combination with paclitaxel
         ii. The requested medication will be used as a single medication if you have received at least one chemotherapy regimen (type of cancer treatment) for metastatic disease

(Criteria continued on next page)

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

GUIDELINES FOR USE (CONTINUED)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. The request is for Herceptin
   2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for trastuzumab
   3. Herceptin will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
   4. You have NOT received prior treatment for metastatic disease

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TRASTUZUMAB-STRF

Generic	Brand				
TRASTUZUMAB-STRF	HERCESSI				

GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-STRF (Hercessi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Breast cancer
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. **If you have breast cancer, approval also requires:**
   1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Ogivri (trastuzumab-dkst)
   3. You meet ONE of the following:
      a. Hercessi will be used as adjuvant (additional) treatment, and you meet ONE of the following:
         i. Hercessi will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         ii. Hercessi will be used as part of a treatment plan with docetaxel and carboplatin
         iii. Hercessi will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
      b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
         i. Hercessi will be used in combination with paclitaxel
         ii. Hercessi will be used as a single medication if you have received at least one chemotherapy regimen (type of cancer treatment) for metastatic disease

(Criteria continued on next page)

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TRASTUZUMAB-STRF

GUIDELINES FOR USE (CONTINUED)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
   2. Hercessi will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
   3. You have NOT received prior treatment for metastatic disease

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TRAZODONE

Generic	Brand				
TRAZODONE HCL	RALDESY				

GUIDELINES FOR USE

Our guideline named **TRAZODONE (Raldesy)** requires the following rule(s) be met for approval:
You have major depressive disorder (a type of mental illness)
You have a contraindication to (harmful for you to use) OR are unable to swallow trazodone tablets

Effective: 04/01/25

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TREMELIMUMAB-ACTL (NSA)

Generic	Brand				
TREMELIMUMAB-ACTL	IMJUDO				

GUIDELINES FOR USE

Our guideline named **TREMELIMUMAB-ACTL (Imjudo)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Unresectable hepatocellular carcinoma (uHCC: a type of liver cancer that cannot be removed by surgery)
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

If you have unresectable hepatocellular carcinoma, approval also requires:

- You are 18 years of age or older
- Imjudo will be used in combination with Imfinzi (durvalumab)
- You have not received previous treatment with Imjudo in your lifetime

If you have metastatic non-small cell lung cancer, approval also requires:

- You are 18 years of age or older
- You do not have sensitizing epidermal growth factor receptor (EGFR: a type of protein) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (a type of abnormal gene)
- Imjudo will be used in combination with Imfinzi (durvalumab) and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin)
- You have not received a total of 5 doses of Imjudo in your lifetime

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TREPROSTINIL-ORENITRAM

Generic	Brand				
TREPROSTINIL DIOLAMINE	ORENITRAM ER				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL-ORENITRAM** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. You do NOT have severe hepatic (liver) impairment
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL-ORENITRAM** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)

Effective: 07/01/25

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TREPROSTINIL-REMODULIN

Generic	Brand				
TREPROSTINIL SODIUM	REMODULIN, TREPROSTINIL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL-REMODULIN** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension (PAH: a type of heart and lung condition) is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units
D. **For new start requests of Remodulin (treprostinil), approval also requires ONE of the following:**
    1. You are intermediate or high risk
    2. You have tried or have a contraindication to (harmful for you to use) TWO of the following clinical standard of care medications from different medication classes:
        a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
        b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
        c. Oral cGMP stimulator (such as Adempas [riociguat])
E. **If you are continuing current Remodulin (treprostinil) therapy from a hospital discharge, there is no additional requirement for approval.**

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TREPROSTINIL-REMODULIN

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL-REMODULIN** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)

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TREPROSTINIL-TYVASO DPI

Generic	Brand				
TREPROSTINIL	TYVASO DPI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL-TYVASO DPI** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

B. **If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension (PAH: a type of heart and lung condition) diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension [a type of heart and lung condition]) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension [a type of heart and lung condition]) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension [a type of heart and lung condition]) greater than 2 Wood units

C. **If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension [a type of heart and lung condition]) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension [a type of heart and lung condition]) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension [a type of heart and lung condition]) greater than 2 Wood units

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TREPROSTINIL-TYVASO DPI

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL-TYVASO DPI** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

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TREPROSTINIL-TYVASO

Generic	Brand				
TREPROSTINIL	TYVASO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL-TYVASO** requires the following rule(s) be met for approval:

You have ONE of the following:

- Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:

- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:

- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
- Your pulmonary hypertension diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
  - Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
  - Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

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TREPROSTINIL-TYVASO

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL-TYVASO** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

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TREPROSTINIL-YUTREPIA

Generic	Brand				
TREPROSTINIL SODIUM	YUTREPIA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TREPROSTINIL-YUTREPIA** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

B. **If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

C. **If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary hypertension diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

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TREPROSTINIL-YUTREPIA

RENEWAL CRITERIA

Our guideline named **TREPROSTINIL-YUTREPIA** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

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TRIENTINE CAPSULE

Generic	Brand				
TRIENTINE HCL	SYPRINE, CLOVIQUE, TRIENTINE HCL				

GUIDELINES FOR USE

Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rule(s) be met for approval:

A. You have Wilson's disease (a type of genetic disorder)
B. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
C. The requested medication will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
D. You have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine (Depen, Cuprimine)
E. You meet ONE of the following:
    1. You have genetic testing confirming an ATP7B mutation (an abnormal change in a type of gene)
    2. You meet ONE of the following:
        a. You have a 24-hour urinary copper excretion (a type of lab test) (greater than 40 micrograms/24 hours)
        b. You have a liver biopsy (removal of cells or tissue from the liver for examination) with copper dry weight greater than 75 micrograms/gram
        c. You have a serum ceruloplasmin (a type of lab test) level less than 20mg/dL

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TRIENTINE TABLET

Generic	Brand				
TRIENTINE TETRAHYDROCHLORIDE	CUVRIOR				

GUIDELINES FOR USE

Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rule(s) be met for approval:

A. You have Wilson's disease (a type of genetic disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
D. Cuvrior will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
E. You have tried the clinical standard of care medication: penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
F. You have tried the preferred medication: trientine hydrochloride (Syprine)
G. You meet ONE of the following:
    1. You have genetic testing confirming an ATP7B mutation (an abnormal change in a type of gene)
    2. You meet ONE of the following:
        a. You have a 24-hour urinary copper excretion (a type of lab test) (greater than 40 micrograms/24 hours)
        b. You have a liver biopsy (removal of cells or tissue from the liver for examination) with copper dry weight greater than 75 micrograms/gram
        c. You have a serum ceruloplasmin (a type of lab test) level less than 20mg/dL

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TRIFLURIDINE/TIPIRACIL

Generic	Brand			
TRIFLURIDINE/ TIPIRACIL HCL	LONSURF			

GUIDELINES FOR USE

Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic colorectal cancer (a type of digestive system cancer that has spread to other parts of the body)
   2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lonsurf will be used as a single agent OR in combination with bevacizumab
   3. You had previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) in combination with an anti-VEGF biological therapy such as Zaltrap (ziv-aflibercept) or Cyramza (ramucirumab)
   4. If your metastatic colorectal cancer is RAS wild-type (a type of gene), you also had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You had previous treatment with at least two prior lines of chemotherapy (drugs used to treat cancer) that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

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TRIHEPTANOIN

Generic	Brand				
TRIHEPTANOIN	DOJOLVI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. Your diagnosis is confirmed by TWO of the following:
    1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
    2. Low enzyme activity in cultured fibroblasts (a type of cell found in the body)
    3. One or more known pathogenic mutations (abnormal changes) in CPT2, ACADVL, HADHA, or HADHB (types of genes)
C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [a type of heart condition])
D. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or physician specialist in medical genetics/inherited metabolic disorders
E. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: commercial MCT oil (a medical food product)

RENEWAL CRITERIA

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. You have experienced a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

Effective: 05/13/26

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TRILACICLIB (NSA)

Generic	Brand				
TRILACICLIB DIHYDROCHLORIDE	COSELA				

GUIDELINES FOR USE

Our guideline named **TRILACICLIB (Cosela)** requires the following rule(s) be met for approval:
You have extensive-stage small cell lung cancer
You are 18 years of age or older
Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression (decreased bone marrow activity causing fewer red blood cells, white blood cells, and platelets)
Cosela will be given prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

Effective: 07/01/21

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TRIPTORELIN-TRELSTAR (NSA)

Generic	Brand				
TRIPTORELIN PAMOATE	TRELSTAR				

GUIDELINES FOR USE

Our guideline named **TRIPTORELIN-TRELSTAR** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

B. **If you have gender dysphoria, approval also requires:**
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

Effective: 07/01/26

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TRIPTORELIN-TRIPTODUR (NSA)

Generic	Brand				
TRIPTORELIN PAMOATE	TRIPTODUR				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRIPTORELIN-TRIPTODUR** requires the following rule(s) be met for approval:

You have ONE of the following diagnoses:

- Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
- Central precocious puberty (CPP: early sexual development in girls and boys)

If you are female and have central precocious puberty, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
- You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
- You are/were younger than 8 years of age when your condition started
- There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

If you are male and have central precocious puberty, approval also requires:

- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
- You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
- You are/were younger than 9 years of age when your condition started
- There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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TRIPTORELIN-TRIPTODUR (NSA)

RENEWAL CRITERIA

NOTE: For the diagnosis of gender dysphoria, please refer to the Initial Criteria section.

Our guideline named **TRIPTORELIN-TRIPTODUR** requires the following rule(s) be met for renewal:
You have central precocious puberty (CPP: early sexual development in girls and boys)
Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
You have not reached the actual age which corresponds to your current pubertal age

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Effective: 01/23/23

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TROFINETIDE

Generic	Brand				
TROFINETIDE	DAYBUE, DAYBUE STIX				

GUIDELINES FOR USE

Our guideline named **TROFINETIDE (Daybue, Daybue Stix)** requires the following rule(s) be met for approval:
You have Rett syndrome (a type of nervous system disorder)
You are 2 years of age or older

Effective: 01/26/26

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TUCATINIB

Generic	Brand				
TUCATINIB	TUKYSA				

GUIDELINES FOR USE

Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced unresectable or metastatic breast cancer (cancer that cannot be removed with surgery or has spread to other parts of the body)
   2. Unresectable or metastatic colorectal cancer (a type of digestive cancer that cannot be removed with surgery or has spread to other parts of the body)

B. **If you have advanced unresectable or metastatic breast cancer, approval also requires:**
   1. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   2. You have received at least one anti-HER2-based treatment (trastuzumab or trastuzumab with pertuzumab) for metastatic (has spread to other parts of the body) disease
   3. Tukysa will be used in combination with trastuzumab and capecitabine

C. **If you have unresectable or metastatic colorectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your colorectal cancer is RAS wild-type (a type of gene), human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   3. Your cancer has progressed (worsened) following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (medications used to treat cancer)
   4. Tukysa will be used in combination with trastuzumab

Effective: 05/05/25

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UBLITUXIMAB-XIIY

Generic	Brand				
UBLITUXIMAB-XIIY	BRIUMVI				

GUIDELINES FOR USE

Our guideline named **UBLITUXIMAB-XIIY (Briumvi)** requires the following rules be met for approval:

You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)

You are 18 years of age or older

You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

Effective: 01/01/26

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UBROGEPANT

Generic	Brand				
UBROGEPANT	UBRELVY				

GUIDELINES FOR USE

Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:
The request is for the acute (quick onset) treatment of migraines (a type of headache)
You are 18 years of age or older
You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute (quick onset) treatment of migraines (a type of headache)
You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

Effective: 04/01/26

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UPADACITINIB

Generic	Brand				
UPADACITINIB	RINVOQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   8. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   9. Giant cell arteritis (GCA: a type of inflammatory condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Enbrel [etanercept])

D. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and are switching to Rinvoq
      b. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
      c. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)
   5. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical phosphodiesterase-4 (PDE-4) inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast]), topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof]), topical Janus kinase (JAK) inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

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INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty), OR you have received at least one approved systemic therapy (treatment that targets the entire body such as Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable (not recommended)

F. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty), OR you have received at least one approved systemic therapy (treatment that targets the entire body such as Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable (not recommended)

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INITIAL CRITERIA (CONTINUED)

G. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

H. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Cimzia [certolizumab])
   5. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   6. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Rinvoq
      b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
      c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

I. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

J. **If you have giant cell arteritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)

RENEWAL CRITERIA

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   8. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   9. Giant cell arteritis (GCA: a type of inflammatory condition)

(Renewal criteria continued on next page)

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have shown improvement while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

F. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

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RENEWAL CRITERIA (CONTINUED)

G. **If you have ankylosing spondylitis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

H. **If you have non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)

I. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

J. **If you have giant cell arteritis, renewal also requires:**
   1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)

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URIDINE TRIACETATE

Generic	Brand			
URIDINE TRIACETATE	XURIDEN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:

A. You have hereditary orotic aciduria (HOA a type of rare genetic disorder)
B. Therapy is prescribed by or in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)
C. Your HOA diagnosis is confirmed by ALL of the following:
    1. You have a genetic mutation (abnormal change in gene) in the uridine monophosphate synthase (UMPS) gene
    2. You have elevated urine orotic acid levels (high levels of a type of substance in the rune) according to your age-specific reference range

RENEWAL CRITERIA

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:

A. You have hereditary orotic aciduria (HOA: a type of rare genetic disorder)
B. You have had improvement from baseline (before treatment) or stabilization of age dependent hematologic parameters (blood lab tests such as neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) while on treatment with Xuriden

Effective: 01/01/25

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USTEKINUMAB

Generic	Brand				
USTEKINUMAB	STELARA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB (Stelara)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   2. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR you have psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
   3. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are 6 to 11 years of age and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab)
   b. You are 12 to 17 years of age and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Icotyde (icotrokinra)
   c. You are 18 years of age or older and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you use) TWO of the following preferred medications:
         1. Tremfya (guselkumab)
         2. Skyrizi (risankizumab-rzaa)
         3. Enbrel (etanercept)
         4. Otezla (apremilast)
         5. Taltz (ixekizumab)
         6. Sotyktu (deucravacitinib)
         7. Bimzelx (bimekizumab-bkzx)
         8. Adalimumab-ryvk/adalimumab-aaty
         9. Icotyde (icotrokinra)

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
            1. Enbrel (etanercept)
            2. Otezla (apremilast)
            3. Tremfya (guselkumab)
            4. Skyrizi (risankizumab-rzaa)
            5. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
            6. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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INITIAL CRITERIA (CONTINUED)

b. You are 18 years of age or older and meet ALL of the following:
   i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      1. Enbrel (etanercept)
      2. Otezla (apremilast)
      3. Tremfya (guselkumab)
      4. Skyrizi (risankizumab-rzaa)
      5. Taltz (ixekizumab)
      6. Bimzelx (bimekizumab-bkzx)
      7. Sotyktu (deucravacitinib)
      8. Adalimumab-ryvk/adalimumab-aaty
      9. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      10. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   3. You meet ONE of the following:
      a. You are 2 to 5 years of age AND meet the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      b. You are 6 to 17 years of age AND meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
      c. You are 18 years of age or older and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
            1. Skyrizi (risankizumab-rzaa)
            2. Tremfya (guselkumab)
            3. Omvoh (mirikizumab-mrkz)
            4. Adalimumab-ryvk/adalimumab-aaty
            5. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Skyrizi (risankizumab-rzaa)
      b. Tremfya (guselkumab)
      c. Omvoh (mirikizumab-mrkz)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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USTEKINUMAB

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB (Stelara)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You meet ONE of the following:
      a. You are 6 to 11 years of age and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab)
      b. You are 12 to 17 years of age and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Icotyde (icotrokinra)

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

c. You are 18 years of age or older and meet ALL of the following:
   i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   ii. You have tried or have a contraindication to (harmful for you use) TWO of the following preferred medications:
      1. Tremfya (guselkumab)
      2. Skyrizi (risankizumab-rzaa)
      3. Enbrel (etanercept)
      4. Otezla (apremilast)
      5. Taltz (ixekizumab)
      6. Sotyktu (deucravacitinib)
      7. Bimzelx (bimekizumab-bkzx)
      8. Adalimumab-ryvk/adalimumab-aaty
      9. Icotyde (icotrokinra)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
            1. Enbrel (etanercept)
            2. Otezla (apremilast)
            3. Tremfya (guselkumab)
            4. Skyrizi (risankizumab-rzaa)
            5. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
            6. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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RENEWAL CRITERIA (CONTINUED)

b. You are 18 years of age or older and meet ALL of the following:
   i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      1. Enbrel (etanercept)
      2. Otezla (apremilast)
      3. Tremfya (guselkumab)
      4. Skyrizi (risankizumab-rzaa)
      5. Taltz (ixekizumab)
      6. Bimzelx (bimekizumab-bkzx)
      7. Sotyktu (deucravacitinib)
      8. Adalimumab-ryvk/adalimumab-aaty
      9. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      10. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You meet ONE of the following:
      a. You are 2 to 5 years of age AND meet the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      b. You are 6 to 17 years of age AND meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
      c. You are 18 years of age or older and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
            1. Skyrizi (risankizumab-rzaa)
            2. Tremfya (guselkumab)
            3. Omvoh (mirikizumab-mrkz)
            4. Adalimumab-ryvk/adalimumab-aaty
            5. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Skyrizi (risankizumab-rzaa)
      b. Tremfya (guselkumab)
      c. Omvoh (mirikizumab-mrkz)
      d. Adalimumab-ryvk/adalimumab-aaty
      e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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USTEKINUMAB-AEKN

Generic	Brand				
USTEKINUMAB-AEKN	USTEKINUMAB-AEKN, SELARSDI				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to the requested medication
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

(Initial criteria continued on next page)

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-AEKN

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-KFCE

Generic	Brand				
USTEKINUMAB-KFCE	YESINTEK				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Yesintek
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-KFCE

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-STBA

Generic	Brand				
USTEKINUMAB-STBA	STEQEYMA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB-STBA (Steqeyma)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Steqeyma
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis a type of skin and joint condition)

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-STBA

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB-STBA (Steqeyma)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

Effective: 07/01/26

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VADADUSTAT

Generic	Brand				
VADADUSTAT	VAFSEO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VADADUSTAT (Vafseo)** requires the following rule(s) be met for approval:
You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
You are 18 years of age or older
You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 3 months
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic (long-term) kidney disease (CKD)
You have a hemoglobin level (a type of blood test) of less than 12 g/dL while treated with an erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa]), and you will discontinue ESA therapy before starting Vafseo
You will NOT use Vafseo concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Jesduvroq [daprodustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

RENEWAL CRITERIA

Our guideline named **VADADUSTAT (Vafseo)** requires the following rule(s) be met for renewal:
You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
You have a hemoglobin level (a type of blood test) of at least 10 g/dL OR your hemoglobin level has increased by at least 2 g/dL from your baseline level (before treatment)
You will NOT use Vafseo concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Jesduvroq [daprodustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

Effective: 10/01/25

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VALBENAZINE

Generic	Brand				
VALBENAZINE TOSYLATE	INGREZZA				

GUIDELINES FOR USE

Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have tardive dyskinesia (TD: uncontrolled body movements)
   2. You have chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
   3. You have a history of using a dopamine antagonist (a type of medication such as haloperidol, ziprasidone, metoclopramide) for at least 12 months

Effective: 07/01/26

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VAMOROLONE

Generic	Brand				
VAMOROLONE	AGAMREE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 2 years of age and older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have tried prednisone or prednisolone for at least 6 months
F. You meet ONE of the following:
    1. Prednisone or prednisolone did not work for you, and you meet ALL of the following:
        a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
        b. There is no steroid myopathy (muscle disease due to steroid use)
        c. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
    2. You have experienced a significant adverse effect (side effects such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

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VAMOROLONE

RENEWAL CRITERIA

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for renewal:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. **If you are currently ambulatory (can walk), approval also requires:**
   1. You have shown improvement while on Agamree as measured by a standard set of ambulatory or functional status measures (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
C. **If you are currently non-ambulatory (cannot walk), approval also requires:**
   1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength while on Agamree as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

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VANDETANIB

Generic	Brand			
VANDETANIB	CAPRELSA			

GUIDELINES FOR USE

Our guideline for **VANDETANIB (Caprelsa)** requires **ONE** of the following rule(s) be met for approval:

A. You are currently stable on the requested medication
B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery and has spread to nearby tissue, lymph nodes, or other parts of the body)

Effective: 01/01/25

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VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

Generic	Brand				
VANZACAFTOR/ TEZACAF/ DEUTIVACAF	ALYFTREK				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You have at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (a type of gene) that is either responsive to Alyftrek based on clinical or in vitro data (testing outside of the body in a tube) or that results in the production of CFTR protein

RENEWAL CRITERIA

Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You have experienced an improvement in your clinical status
C. You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

Effective: 05/09/26

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VARENICLINE

Generic	Brand				
VARENICLINE TARTRATE	TYRVAYA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for approval:
You have dry eye disease (DED: a type of eye condition)
Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
You have at least ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)

RENEWAL CRITERIA

Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for renewal:
You have dry eye disease (DED: a type of eye condition)
You have demonstrated improvement of dry eye disease (the treatment is working)

Effective: 08/11/25

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VEDOLIZUMAB

Generic	Brand				
VEDOLIZUMAB	ENTYVIO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

(Initial criteria continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      g. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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VEDOLIZUMAB

RENEWAL CRITERIA

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe Crohn's disease, renewal also requires:**
   1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

(Renewal criteria continued on next page)

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RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe ulcerative colitis, renewal also requires:**
   1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      g. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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VELAGLUCERASE ALFA

Generic	Brand				
VELAGLUCERASE ALFA	VPRIV				

GUIDELINES FOR USE

Our guideline named **VELAGLUCERASE ALFA (Vpriv)** requires the following rule(s) be met for approval:

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 4 years of age or older
C. You had a trial of or contraindication to (harmful for you to use) Elelyso

Effective: 02/09/26

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VELMANASE ALFA-TYCV (NSA)

Generic	Brand				
VELMANASE ALFA-TYCV	LAMZEDE				

GUIDELINES FOR USE

Our guideline named **VELMANASE ALFA-TYCV (Lamzede)** requires the following rule(s) be met for approval:

A. You have non-central nervous system manifestations (symptoms outside of the brain and spinal cord) of alpha-mannosidosis (a rare genetic condition)

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VEMURAFENIB

Generic	Brand			
VEMURAFENIB	ZELBORAF			

GUIDELINES FOR USE

Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   2. Erdheim-Chester Disease (a type of multisystem mutation)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E mutation (a type of abnormal change in a gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

C. **If you have Erdheim-Chester Disease, approval also requires:**
   1. You have a BRAF V600 mutation (a type of abnormal change in a gene)

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VENETOCLAX

Generic	Brand			
VENETOCLAX	VENCLEXTA			

GUIDELINES FOR USE

Our guideline named **VENETOCLAX (Venclexta)** requires that the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   3. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

B. **If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:**
   1. You are 18 years of age or older

C. **If you have acute myeloid leukemia, approval also requires:**
   1. You are newly diagnosed (such as you are starting or previously started Venclexta treatment at the time your condition was identified)
   2. Venclexta will be used in combination with azacitidine, decitabine, Inqovi (decitabine/cedazuridine), or low-dose cytarabine
   3. You meet ONE of the following:
      a. You are 75 years of age or older
      b. You are 18 years of age or older with comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)

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VERICIGUAT

Generic	Brand				
VERICIGUAT	VERQUVO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:
You have chronic heart failure (HF: a type of heart condition)
You are 18 years of age or older
You have an ejection fraction (heart function) of less than 45 percent
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
You will NOT use Verquvo concurrently (at the same time) with Adempas (riociguat) or phosphodiesterase-5 (PDE-5) inhibitors (such as vardenafil, tadalafil)
You have tried and will continue use, or you have a contraindication to (harmful for you to use) ONE medication from EACH of the following Guideline-Directed Medical Therapy (GDMT: a type of medical treatment) medication classes:
- Angiotensin converting enzyme (ACE) inhibitor (such as enalapril, lisinopril), angiotensin II receptor blocker (ARB) (such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI) (such as Entresto [sacubitril/valsartan])
- Beta-blocker (such as bisoprolol, carvedilol, metoprolol succinate)
- Aldosterone antagonist (spironolactone or eplerenone)
- Sodium-glucose transporter-2 (SGLT2) inhibitor indicated for heart failure (a type of heart condition) (such as Farxiga [dapagliflozin], Jardiance [empagliflozin], Inpefa [sotagliflozin])

You are high-risk with worsening heart failure (a type of heart condition), as shown by hospitalization for heart failure or the need for intravenous (IV: injection into the veins) diuretics (type of medication)

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VERICIGUAT

RENEWAL CRITERIA

Our guideline named **VERICIGUAT (Verquvo**) requires the following rule(s) be met for renewal:
You have chronic heart failure (a type of heart condition)
You have an ejection fraction (heart function) of less than 45 percent
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
You will NOT use Verquvo concurrently (at the same time) with Adempas (riociguat) or phosphodiesterase-5 (PDE-5) inhibitors (such as vardenafil, tadalafil)
You have tried and will continue use, or you have a contraindication to (harmful for you to use) ONE medication from EACH of the following Guideline-Directed Medical Therapy (GDMT: a type of medical treatment) medication classes:
- Angiotensin converting enzyme (ACE) inhibitor (such as enalapril, lisinopril), angiotensin II receptor blocker (ARB) (such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI) (such as Entresto [sacubitril/valsartan])
- Beta-blocker (such as bisoprolol, carvedilol, metoprolol succinate)
- Aldosterone antagonist (spironolactone or eplerenone)
- Sodium-glucose transporter-2 (SGLT2) inhibitor indicated for heart failure (a type of heart condition) (such as Farxiga [dapagliflozin], Jardiance [empagliflozin], Inpefa [sotagliflozin])

Effective: 10/01/25

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VESTRONIDASE ALFA-VJBK (NSA)

Generic	Brand			
VESTRONIDASE ALFA-VJBK	MEPSEVII			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for approval:

You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)

The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders

You have a documented urinary GAG (glycosaminoglycan: type of chemical that builds up when your body cannot break it down) level of greater than three times the upper level of normal based on the laboratory test

Your diagnosis of Mucopolysaccharidosis VII is confirmed by documentation of beta-glucuronidase enzyme activity deficiency (you don't have a protein that breaks down a chemical) or genetic testing

You have at least ONE of the following clinical signs of Mucopolysaccharidosis VII:
- Enlarged liver and spleen
- Joint limitations
- Airway obstructions or pulmonary (lung/breathing) dysfunction

You have not undergone successful bone marrow or stem cell treatment for Mucopolysaccharidosis VII

You have limitation in mobility, but you still have ambulatory (walking) capacity for the six-minute walk test (6MWT) to be measured and evaluated

RENEWAL CRITERIA

Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for renewal:

You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)

You have improved, maintained, or demonstrated less than expected decline in ambulatory (walking) ability based on a six-minute walk test compared to baseline

Effective: 07/01/20

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VIGABATRIN

Generic	Brand				
VIGABATRIN	SABRIL, VIGABATRIN, VIGADRONE, VIGPODER				

GUIDELINES FOR USE

INITIAL CRITERIA (CONTINUED)

Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Refractory complex partial seizures (a type of seizure)
- Infantile spasms (a type of seizure disorder in infancy and childhood)

If you have refractory complex partial seizures, approval also requires:
- You are 2 years of age or older
- The requested medication will be used as adjunctive (add-on) therapy
- The potential benefits outweigh the potential risk of vision loss
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have tried or have a contraindication to (harmful for you to use) THREE antiepileptic medications, at least two of which must be generic (medications used to treat seizures such as carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)

If you have infantile spasms, approval also requires:
- You are 1 month to 2 years of age
- The requested medication will be used as monotherapy (one drug treatment)
- The potential benefits outweigh the potential risk of vision loss
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)

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VIGABATRIN

RENEWAL CRITERIA

Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for renewal:
You have ONE of the following:
Refractory complex partial seizures (a type of seizure)
Infantile spasms (a type of seizure disorder in infancy and childhood)
If you have infantile spasms, renewal also requires:
You are 1 month to 2 years of age

Effective: 10/01/25

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VIGABATRIN SOLUTION

Generic	Brand				
VIGABATRIN	VIGAFYDE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VIGABATRIN SOLUTION (Vigafyde)** requires the following rule(s) be met for approval:
You have infantile spasms (a type of seizure disorder in infancy and childhood)
You are 1 month to 2 years of age
Vigafyde will be used as monotherapy (one medication treatment)
The potential benefits outweigh the potential risk of vision loss
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
You have tried or have a contraindication to (harmful for you to use) generic vigabatrin powder for solution

RENEWAL CRITERIA

Our guideline named **VIGABATRIN SOLUTION (Vigafyde)** requires the following rule(s) be met for renewal:
You have infantile spasms (a type of seizure disorder in infancy and childhood)
You are 1 month to 2 years of age

Effective: 10/01/25

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VILOBELIMAB (NSA)

Generic	Brand				
VILOBELIMAB	GOHIBIC				

GUIDELINES FOR USE

Our guideline named **VILOBELIMAB (Gohibic)** will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

Effective: 10/01/23

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VILTOLARSEN (NSA)

Generic	Brand				
VILTOLARSEN	VILTEPSO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VILTOLARSEN (Viltepso)** requires the following rule(s) be met for approval:

You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)

You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 53 skipping (a process that allows a protein to still function with sections of faulty genetic code)

Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center

You are ambulatory (able to move and walk)

You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **VILTOLARSEN (Viltepso)** requires ONE of the following rule(s) be met for renewal:

You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)

You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

Effective: 01/01/21

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VIMSELTINIB

Generic	Brand				
VIMSELTINIB	ROMVIMZA				

GUIDELINES FOR USE

Our guideline named **VIMSELTINIB (Romvimza)** requires the following rule(s) be met for approval:
You have symptomatic tenosynovial giant cell tumor (TGCT: a type of tumor that affects joints)
You are 18 years of age or older
Surgical resection (removal by surgery) of the tumor may cause worsening functional limitation or severe morbidity (illness)

Effective: 04/01/25

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VISMODEGIB

Generic	Brand				
VISMODEGIB	ERIVEDGE				

GUIDELINES FOR USE

Our guideline named **VISMODEGIB (Erivedge)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic basal cell carcinoma (a type of skin cancer that has spread to other parts of the body)
   2. Locally advanced basal cell carcinoma (a type of skin cancer that has spread from where it started to nearby tissue or lymph nodes)

B. **If you have metastatic basal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older

C. **If you have locally advanced basal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has returned after surgery OR you are not a candidate for surgery or radiation

Effective: 02/01/26

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VOCLOSPORIN

Generic	Brand				
VOCLOSPORIN	LUPKYNIS				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:
You have active lupus nephritis (LN: a type of immune condition that affects the kidneys)
You are 18 years of age or older
Lupkynis will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids [such as prednisone])
Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)

RENEWAL CRITERIA

Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You have improvement in renal response from baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

Effective: 01/01/25

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VONOPRAZAN

Generic	Brand				
VONOPRAZAN/AMOXICILLIN	VOQUEZNA DUAL PAK				
VONOPRAZAN/AMOXICILLIN /CLARITH	VOQUEZNA TRIPLE PAK				
VONOPRAZAN FUMARATE	VOQUEZNA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VONOPRAZAN (Voquezna Dual Pak, Voquezna Triple Pak, Voquezna)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. *Helicobacter pylori (H. pylori*: a type of bacteria*)* infection
   2. Erosive esophagitis (a type of digestive disorder)
   3. Non-erosive gastroesophageal reflux disease (a type of digestive disorder)

B. **If you have a *Helicobacter pylori* infection, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your request is for Voquezna 20mg in combination with amoxicillin
      b. Your request is for Voquezna 20mg in combination with amoxicillin and clarithromycin
      c. Your request is for Voquezna Dual Pak
      d. Your request is for Voquezna Triple Pak

C. **If you have erosive esophagitis, approval also requires:**
   1. Your request is for Voquezna
   2. You are 18 years of age or older
   3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole) at a maximum dose for 8 weeks

D. **If you have non-erosive gastroesophageal reflux disease, approval also requires:**
   1. Your request is for Voquezna 10mg
   2. You are 18 years of age or older
   3. You do not have a previous treatment failure (medication did not work) with Voquezna in the last 12 months
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks

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VONOPRAZAN

RENEWAL CRITERIA

NOTE: For the diagnosis of *Helicobacter pylori* (*H. pylori*) infection or non-erosive gastroesophageal reflux disease, please refer to the Initial Criteria section.

Our guideline named **VONOPRAZAN (Voquezna)** requires the following rule(s) be met for renewal:

A. You have erosive esophagitis (a type of digestive disorder)
B. Your request is for Voquezna
C. You have maintained a clinical response on Voquezna (the treatment is working)

Effective: 08/27/26

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VORASIDENIB

Generic	Brand				
VORASIDENIB CITRATE	VORANIGO				

GUIDELINES FOR USE

Our guideline named **VORASIDENIB (Voranigo)** requires the following rule(s) be met for approval:

A. You have Grade 2 astrocytoma or oligodendroglioma (types of brain cancer)
B. You are 12 years of age or older
C. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation (abnormal changes in types of genes that increase the risk of certain diseases)
D. Voranigo will be used following surgery, including biopsy (removal of cells or tissue from the body for examination), sub-total resection (partial removal of tumor), or gross total resection (complete removal of tumor)

Effective: 09/01/24

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VORINOSTAT

Generic	Brand				
VORINOSTAT	ZOLINZA				

GUIDELINES FOR USE

Our guideline named **VORINOSTAT (Zolinza)** requires the following rule(s) be met for approval:

A. You have cutaneous T-cell lymphoma (a type of blood cancer that affects the skin)
B. You have progressive (worsening), persistent (continues to exist), or recurrent (returns) disease on or following two systemic therapies (a type of medication that goes to the entire body such as Targretin [bexarotene], Istodax, [romidepsin])

Effective: 07/01/26

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VOSORITIDE

Generic	Brand				
VOSORITIDE	VOXZOGO				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VOSORITIDE (Voxzogo)** requires the following rule(s) be met for approval:
You have achondroplasia (a type of bone condition)
You have open epiphyses (the end part of a long bone)
Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), orthopedist (a type of doctor who specializes in bones, joints, muscles, ligaments, tendons and nerves), or medical geneticist (doctor who treats gene disorders)
You will NOT use Voxzogo concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Yuviwel [navepegritide]) for the treatment of achondroplasia (a type of bone condition)

RENEWAL CRITERIA

Our guideline named **VOSORITIDE (Voxzogo)** requires the following rule(s) be met for renewal:
You have achondroplasia (a type of bone condition)
You have experienced an improvement in annual growth velocity (rate of growth) since baseline (before treatment with Voxzogo)
Your epiphyses (the end part of a long bone) remain open
You will NOT use Voxzogo concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Yuviwel [navepegritide]) for the treatment of achondroplasia (a type of bone condition)

Effective: 03/18/26

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VOXELOTOR

Generic	Brand				
VOXELOTOR	OXBRYTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VOXELOTOR (Oxbryta)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (a type of blood disorder)
B. You are 4 years of age or older
C. Your hemoglobin (a type of blood cell) is less than 10.5 g/dL
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
E. You are having symptoms of anemia (a type of blood condition) which are interfering with activities of daily living
F. You had a trial of or contraindication (harmful for) to hydroxyurea
G. **If the request is for the 300 mg tablets for oral suspension, approval also requires ONE of the following:**
    1. You weigh less than 40 kilograms
    2. You weigh 40 kilograms or more and meet ALL of the following:
        a. You have tried or have a contraindication (harmful for) to Oxbryta 500mg tablets
        b. You are unable to swallow Oxbryta 500mg tablets

RENEWAL CRITERIA

Our guideline named **VOXELOTOR (Oxbryta)** requires the following rule(s) be met for renewal:

A. You have sickle cell disease (a type of blood disorder)
B. You have maintained an improvement in symptoms associated with anemia (a type of blood condition)

Effective: 01/16/23

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VUTRISIRAN

Generic	Brand				
VUTRISIRAN SODIUM	AMVUTTRA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VUTRISIRAN (Amvuttra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   2. Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)

B. **If you have hereditary transthyretin-mediated amyloidosis with polyneuropathy, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR (a rare genetic disorder with widespread nerve pain/damage) specialist, or medical geneticist (doctor who treats gene disorders)
   3. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 OR Polyneuropathy Disability [PND: a tool used to evaluate disease severity] stage I to IIIb polyneuropathy)
   4. You will NOT use Amvuttra concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])
   5. Your diagnosis is confirmed by ONE of the following:
      a. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm presence of TTR (transthyretin) protein
      b. DNA (deoxyribonucleic acid) genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

(Initial criteria continued on next page)

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VUTRISIRAN

INITIAL CRITERIA (CONTINUED)

C. **If you have cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
   3. You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
   4. Your diagnosis is confirmed by ONE of the following:
      a. Bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)
      b. Biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein
   5. You will NOT use Amvuttra concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby], tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)

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VUTRISIRAN

RENEWAL CRITERIA

Our guideline named **VUTRISIRAN (Amvuttra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   2. Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)

B. **If you have hereditary transthyretin-mediated amyloidosis with polyneuropathy, renewal also requires:**
   1. You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage 4 polyneuropathy, as shown by functional decline (such as being wheelchair-bound, being bedridden)
   2. You will NOT use Amvuttra concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])

C. **If you have cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis, renewal also requires:**
   1. You will NOT use Amvuttra concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby], tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)

Effective: 06/10/26

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ZANIDATAMAB-HRII

Generic	Brand				
ZANIDATAMAB-HRII	ZIIHERA				

GUIDELINES FOR USE

Our guideline named **ZANIDATAMAB-HRII (Ziihera)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Biliary tract cancer (BTC: a type of bile duct or gallbladder cancer)
   2. Gastric, gastroesophageal junction, or esophageal adenocarcinoma (GEA: a type of digestive system cancer)

B. **If you have biliary tract cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is previously treated, unresectable (unable to remove by surgery) or metastatic (cancer that has spread to other parts of the body)
   3. Your cancer is human epidermal growth factor receptor 2 (HER2)-positive immunohistochemistry 3+ (IHC 3+), as detected by a Food and Drug Administration (FDA)-authorized test

C. **If you have gastric, gastroesophageal junction, or esophageal adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is unresectable (cannot be removed by surgery) locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body)
   3. You meet ONE of the following:
      i. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or IHC 2+/ISH+), as detected by a Food and Drug Administration (FDA)-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (such as fluorouracil, capecitabine) and platinum-containing chemotherapy (such as cisplatin, oxaliplatin) and Tevimbra (tislelizumab-jsgr)
      ii. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+), as detected by a Food and Drug Administration (FDA)-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (such as fluorouracil, capecitabine) and platinum-containing chemotherapy (such as cisplatin, oxaliplatin)

Effective: 08/29/26

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ZANUBRUTINIB

Generic	Brand				
ZANUBRUTINIB	BRUKINSA				

GUIDELINES FOR USE

Our guideline named **ZANUBRUTINIB (Brukinsa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Mantle cell lymphoma (MCL: a type of blood cancer)
   2. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
   3. Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer that has returned or did not respond to treatment)
   4. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   5. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   6. Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or did not respond to treatment)

B. **If you have mantle cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received at least ONE prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Calquence (acalabrutinib)

C. **If you have Waldenstrom's macroglobulinemia, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Imbruvica (ibrutinib)

D. **If you have relapsed or refractory marginal zone lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan, such as rituximab)

E. **If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Calquence (acalabrutinib), Imbruvica (ibrutinib)

F. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. Brukinsa will be used in combination with Gazyva (obinutuzumab)
   3. Brukinsa will be used after at least TWO lines of systemic therapy (such as lenalidomide with rituximab)

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ZAVEGEPANT

Generic	Brand				
ZAVEGEPANT HCL	ZAVZPRET				

GUIDELINES FOR USE

Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
The request is for the acute (quick onset) treatment of migraines (a type of headache)
You are 18 years of age or older
You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute (quick onset) treatment of migraines (a type of headache)
You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
You are NOT able to tolerate oral medications

Effective: 04/01/26

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ZERO COPAY OVERRIDE - ASPIRIN

Generic	Brand				
ASPIRIN	ASPIRIN, ASPIRIN EC, VARIOUS				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - ASPIRIN** requires the following rule(s) be met for approval:

You meet ONE of the following:

- Your request is for a generic medication
- Your request is for a multi-source or single source brand medication (a brand name medication) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

Effective: 01/01/26

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ZERO COPAY OVERRIDE - BOWEL PREP

Generic	Brand				
SOD PICOSULF/MAG OX/CITRIC AC	CLENPIQ				
BISAC/NACL/NAHCO3/KCL/PEG 3350	PEG-PREP				
PEG3350/SOD SULF,BICARB,CL/KCL	GAVILYTE-C, GAVILYTE-G, GOLYTELY COLYTE WITH FLAVOR PACKS, PEG 3350-ELECTROLYTE, PEG 3350 AND ELECTROLYTES				
SODIUM CHLORIDE/NAHCO3/ KCL/PEG	NULYTELY, NULYTELY WITH FLAVOR PACKS, GAVILYTE-N, PEG 3350-ELECTROLYTE, TRILYTE WITH FLAVOR PACKETS				
PEG3350/SOD/SUL/NACL /KCL/ASB/C	MOVIPREP, PLENVU, PEG3350/SOD SUL/NACL/KCL/ASB/C				
PEG 3350/SOD SULF, CHLR/POT/MAG	SUFLAVE				
SODIUM, POTASSIUM,MAG SULFATES	SUPREP, SODIUM, POTASSIUM,MAG SULFATES				
SOD SULF/POT CHLORIDE/MAG SULF	SUTAB				

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ZERO COPAY OVERRIDE - BOWEL PREP

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - BOWEL PREP** requires the following rule(s) be met for approval:

A. The requested medication is being used for colorectal cancer screening
B. You are between 45 to 75 years of age
C. You meet ONE of the following:
    1. Your request is for a generic medication or single source brand medication (a brand name medication without a generic available)
    2. Your request is for a multi-source medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

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ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

Generic	Brand				
ANASTROZOLE	ARIMIDEX, ANASTROZOLE				
EXEMESTANE	AROMASIN, EXEMESTANE				
RALOXIFENE HCL	EVISTA, RALOXIFENE HCL				
TAMOXIFEN CITRATE	TAMOXIFEN CITRATE				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION** requires the following rule(s) be met for approval:

A. The requested medication is being used for prevention (risk reduction) of breast cancer
B. You are 35 years of age or older
C. You are requesting a quantity of #1 per day
D. You meet ONE of the following:
    3. Your request is for a generic medication
E. Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

Generic					
CONTRACEPTIVES, ORAL					
CONTRACEPTIVES, TRANSDERMAL					
CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC					
INTRA-UTERINE DEVICES (IUD'S)					
CONTRACEPTIVES, INJECTABLE					
CONTRACEPTIVES, IMPLANTABLE					
CONTRACEPTIVE, INTRAVAGINAL					
DIAPHRAGMS/CERVICAL CAP					
CONDOMS, VARIED					

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - CONTRACEPTIVE** requires that the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. Your request is for a generic or a single source brand medication (a brand name medication without a generic available)
   2. Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

B. If your request is for an oral contraceptive, approval also requires ONE of the following:
   1. Your request is for a quantity of #1 per day
   2. Your request is for a quantity greater than #1 per day AND your doctor has provided medical justification as to why the requested quantity is needed for contraception (such as continuous therapy, skipping placebo pills)

C. If your request is for a condom, approval also requires ONE of the following:
   1. Your request is for a quantity of #60 per prescription fill
   2. Your request is for a quantity greater than #60 per fill AND your doctor has provided medical justification as to why the requested quantity is needed for contraception

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ZERO COPAY OVERRIDE - FLUORIDE

Generic	Brand				
FLUORIDE (SODIUM)	FLURA-DROPS, SOLUVITA, FLUORIDE, SODIUM FLUORIDE, LUDENT FLUORIDE				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - FLUORIDE** requires the following rule(s) be met for approval:

A. You are 6 months to 6 years of age
B. You meet ONE of the following:
    1. Your request is for a generic medication
    2. Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

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ZERO COPAY OVERRIDE - FOLIC ACID

Generic	Brand				
FOLIC ACID	FOLIC ACID				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - FOLIC ACID** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. Your request is for a generic medication
   2. Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication.

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ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

Generic	Brand				
EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	TRUVADA, EMTRICITABINE/ TENOFOVIR DISOPROXIL FUMARATE				
EMTRICITABINE/TENOFOVIR ALAFENAMIDE FUMARATE	DESCOVY				
TENOFOVIR DISOPROXIL FUMARATE	VIREAD, TENOFOVIR DISOPROXIL FUMARATE				
EMTRICITABINE	EMTRIVA, EMTRICITABINE				
CABOTEGRAVIR	APRETUDE				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS** requires the following rule(s) be met for approval:

A. The requested medication is FDA (Food and Drug Administration)-approved for pre-exposure prophylaxis (PrEP) OR recommended by the CDC (Centers for Disease Control and Prevention) PrEP Guidelines
B. The requested medication will NOT be used concurrently (at the same time) with another human immunodeficiency virus (HIV) medication for the treatment of HIV
C. Your request is for a dosing quantity of #1 per day for Truvada (emtricitabine/tenofovir disoproxil fumarate), Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), and Descovy (emtricitabine and tenofovir alafenamide)
D. You meet ONE of the following:
    1. Your request is for a generic or a single source brand medication (a brand name medication without a generic available)
    2. Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

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ZERO COPAY OVERRIDE - SMOKING CESSATION

Generic	Brand				
BUPROPION HCL	ZYBAN, BUROPION HCL SR				
VARENICLINE TARTRATE	CHANTIX, VARENICLINE TARTRATE				
NICOTINE	NICOTROL, NICOTROL NS, NICOTINE PATCH, NICODERM CQ, NICOTINE				
NICOTINE POLACRILEX	NICOTINE GUM, NICOTINE LOZENGE, NICORETTE, VARIOUS				

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - SMOKING CESSATION** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You meet ONE of the following:
    1. Your request is for a generic
    2. Your request is for a multi-source medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

Effective: 03/03/25

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ZERO COPAY OVERRIDE - STATIN

Generic	Brand				
ROSUVASTATIN CALCIUM	CRESTOR, ROSUVASTATIN CALCIUM				
PRAVASTATIN SODIUM	PRAVACHOL, PRAVASTATIN SODIUM				
SIMVASTATIN	ZOCOR, SIMVASTATIN				
ATORVASTATIN CALCIUM	LIPITOR, ATORVASTATIN CALCIUM				
LOVASTATIN, LOVASTATIN EXTENDED-RELEASE	ALTOPREV, LOVASTATIN				
FLUVASTATIN SODIUM , FLUVASTATIN EXTENDED-RELEASE	LESCOL, FLUVASTATIN SODIUM, LESCOL XL, FLUVASTATIN EXTENDED-RELEASE				
PITAVASTATIN CALCIUM	LIVALO, PITAVASTATIN CALCIUM				
PITAVASTATIN MAGNESIUM	ZYPITAMAG, PITAVASTATIN MAGNESIUM				

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE

Our guideline named **ZERO COPAY OVERRIDE - STATIN** requires the following rule(s) be met for approval:

A. You are between 40 to 75 years old
B. You are not concurrently (at the same time) taking any of the below secondary prevention medications for cardiovascular disease (heart disease):
   1. Aspirin/dipyridamole (Aggrenox)
   2. Clopidogrel (Plavix)
   3. Dipyridamole
   4. Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
   5. Prasugrel (Effient)
   6. Ticagrelor (Brilinta)
   7. Ticlopidine
   8. Vorapaxar (Zontivity)
C. The requested quantity is within the low to moderate intensity daily dosage as shown below:
   1. Atorvastatin (Lipitor): 10 - 20 mg
   2. Fluvastatin (Lescol): 20 - 80 mg (40 mg twice daily)
   3. Fluvastatin ER (Lescol XL): 80 mg
   4. Lovastatin: 10 - 40 mg
   5. Pitavastatin calcium (Livalo): 1 - 4 mg
   6. Pravastatin (Pravachol): 10 - 80 mg
   7. Rosuvastatin (Crestor): 5 - 10 mg
D. You meet ONE of the following:
   1. Your request is for a generic medication
   2. Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

Effective: 07/01/26

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ZIFTOMENIB

Generic	Brand				
ZIFTOMENIB	KOMZIFTI				

GUIDELINES FOR USE

Our guideline named **ZIFTOMENIB (Komzifti)** requires the following rule(s) be met for approval:

You have relapsed or refractory acute myeloid leukemia (AML) (a type of blood cancer that has returned or did not respond to treatment)

You are 18 years of age or older

You have a susceptible nucleophosmin 1 (NPM1) mutation (an abnormal change in a type of gene)

You have no satisfactory alternative treatment options

Effective: 12/08/25

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ZILUCOPLAN

Generic	Brand				
ZILUCOPLAN SODIUM	ZILBRYSQ				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for approval:

- You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
- You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
- You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
- You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
- You have tried or have a contraindication to ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)
- You will NOT use Zilbrysq concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
  - You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

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ZILUCOPLAN

RENEWAL CRITERIA

Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for renewal:
You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
You have had clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
You will NOT use Zilbrysq concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

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Effective: 02/01/26

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ZIV-AFLIBERCEPT

Generic	Brand				
ZIV-AFLIBERCEPT	ZALTRAP				

GUIDELINES FOR USE

Our guideline named **ZIV-AFLIBERCEPT** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (a type of digestive tract cancer that has spread to other parts of the body)
B. Your cancer is resistant to (no longer responds) or has progressed (worsened) following an oxaliplatin-containing regimen (a type of cancer treatment such as FOLFOX [leucovorin, fluorouracil, oxaliplatin])
C. You will use Zaltrap in combination with fluorouracil, leucovorin, irinotecan (FOLFIRI: a type of cancer treatment)

Effective: 02/09/26

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ZOLBETUXIMAB-CLZB

Generic	Brand				
ZOLBETUXIMAB-CLZB	VYLOY				

GUIDELINES FOR USE

Our guideline named **ZOLBETUXIMAB-CLZB (Vyloy)** requires the following rule(s) be met for approval:

You have locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue, or has spread to other parts of the body)
You are 18 years of age or older
Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
Your tumors are claudin (CLDN) 18.2 (a type of protein) positive, as determined by a Food and Drug Administration (FDA)-approved test
Vyloy will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (a type of cancer treatment such as mFOLFOX6 [fluorouracil, leucovorin, oxaliplatin], CAPOX [capecitabine, oxaliplatin])

Effective: 02/09/26

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ZONGERTINIB

Generic	Brand				
ZONGERTINIB	HERNEXEOS				

GUIDELINES FOR USE

Our guideline named **ZONGERTINIB (Hernexeos)** requires the following rule(s) be met for approval:

You have unresectable (unable to remove by surgery) or metastatic (cancer that has spread to other parts of the body) non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer)

You are 18 years of age or older

Your tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

Effective: 03/11/26

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ZONISAMIDE

Generic	Brand				
ZONISAMIDE	ZONISADE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ZONISAMIDE (Zonisade)** requires the following rule(s) be met for approval:
You have partial-onset seizures (a type of seizure)
You are 16 years of age or older
Zonisade will be used as adjunctive (add-on) treatment
You have a contraindication to (harmful for you to use) or are unable to swallow zonisamide capsules
You have tried or have a contraindication to (harmful for you to use) THREE antiepileptic medications (medications used to treat seizures, such as carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide capsules, topiramate, lamotrigine)

RENEWAL CRITERIA

Our guideline named **ZONISAMIDE (Zonisade)** requires the following rule(s) be met for renewal:
You have partial-onset seizures (a type of seizure)

Effective: 10/01/25

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ZURANOLONE

Generic	Brand				
ZURANOLONE	ZURZUVAE				

GUIDELINES FOR USE

Our guideline named **ZURANOLONE (Zurzuvae)** requires the following rule(s) be met for approval:

A. You have postpartum depression (PPD: a type of depression that occurs after giving birth)

Effective: 01/01/25

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