Prior Authorization Criteria

Effective July 1, 2024

The following is the listing of Prescryptive Health prior authorization criteria that will be used to evaluate prior authorization requests. Prescryptive Health's prior authorization criteria are based on clinical monographs and National Pharmacy and Therapeutics guidelines. Prior Authorization Criteria will be updated regularly to reflect ongoing changes and is subject to change without notice.

Prior Authorization Requests for Tier 4 Medications and Non-Preferred Medications

Tier 4 and non-preferred medications may be authorized when there is clinical justification for doing so. Clinicians can submit a prior authorization (PA) request to initiate a review with the following steps:

1. Download the Prior Authorization Request Form. This form can be found at: http://www.prescryptive.com/resources/

2. Fax the completed form with supporting documentation to **1 (855) 708-4808** for both standard and urgent requests.

Note: Urgent requests should be clearly labeled "URGENT" at the top of the prior authorization request form.

Abaloparatide (Tymlos)

Specific Therapeutic Class: *Parathyroid hormone analog*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Reauthorization: 12 months (once only)

Diagnosis Considered for Coverage:

- Osteoporosis in postmenopausal females at high risk for fractures or in patients who have failed or are intolerant to other osteoporosis therapies

Prescribing Restriction:

- Quantity Limit*: 80mcg daily (#1 prefilled pen per 30 days)
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Osteoporosis**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Patient is a postmenopausal female at high risk for fractures (defined as a history of osteoporotic fracture or multiple risk factors for fracture)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use bisphosphonates and denosumab (Xgena, Prolia)
  - T-score < -3 OR T-score < -2.5 with high risk of fracture or history of fracture
  - The patient does not have hypocalcemia OR hypocalcemia will be corrected prior to initiating therapy
  - The patient is not at an increased risk for osteosarcoma (defined by having any of the following: Paget disease, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, unexplained elevation of alkaline phosphatase, prior external beam or implant radiation therapy involving the skeleton, or in patients with open epiphyses)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- Total duration of use is less than or equal to 2 years

References: N/A

Abaloparatide (Tymlos)

Last review/revision date: 2/2022

Abatacept (Orencia)

Therapeutic Category: *Antirheumatic, Disease Modifying; Selective T-Cell Costimulation Blocker*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriatic arthritis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis: 125 mg once weekly
  - Juvenile Idiopathic Arthritis, Psoriatic Arthritis
    - 10 to <25 kg: 50 mg weekly
    - 25 to <50 kg: 87. 5 mg weekly
    - 50 kg or more: 125 mg once weekly
- Prescriber restriction: Rheumatologist or Dermatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to at least ONE DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below

Abatacept (Orencia)

        - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e, drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
    - Patient is 2 to 17 years of age
    - Patient has diagnosis of juvenile idiopathic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
    - Patient is 2 to 17 years of age
    - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Psoriatic Arthritis**, approve if:
    - Patient is 2 years of age or older
    - Diagnosis of psoriatic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug is being prescribed by a Rheumatologist or Dermatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids

Abatacept (Orencia)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), guselkumab (Tremfya), ixekizumab (Taltz), tofacitinib (Xeljanz), tofacitinib ER (Xeljanz XR), Risankizumab-Rzaa (Skyrizi), or Upadacitinib (Rinvoq)

III. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 2/2024

Abemaciclib (Verzenio)

Specific Therapeutic Class: *Antineoplastic Agent, Cyclin-Dependent Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer, advanced or metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Quantity Limit: Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient is Hormone receptor (HR) positive
  - Patient is Human epidermal growth factor receptor 2 (HER2) negative
  - One of the following:
    - The requested agent will be used in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women
    - The requested agent will be used in combination with fulvestrant for the treatment of women with disease progression following endocrine therapy
    - The requested agent will be used as monotherapy for the treatment of patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
    - Patient has node-positive, high risk early breast cancer with a Ki-67 score of ≥20%

- For the diagnosis of **Off-Label Indications**, approve if:

Abemaciclib (Verzenio)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 2/2024

Abiraterone (Yonsa, Zytiga)

Specific Therapeutic Class: *Antineoplastic Agent, Antiandrogen*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prostate cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*: Authorized quantity sufficient for a 30 day supply
- Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Metastatic, Castration-Resistant Prostate Cancer**, approve if:
  - One of the following:
    - Prescription is written for generic 250mg tablets
    - All of the following:
      a. Patient is 18 years of age or older
      b. Patient will not receive dual therapy with another androgen receptor inhibitor
      c. If the request is for abiraterone (Zytiga), it will be used in combination with prednisone
      d. If the request is for abiraterone (Yonsa), all of the following:
         i. It will be used in combination with methylprednisolone
         ii. There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic abiraterone OR the request is for generic abiraterone
      e. One of the following:
         i. Patient has had bilateral orchiectomy
         ii. The requested agent will be used in combination with a gonadotropin-releasing hormone (GnRH) analog
      f. There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic abiraterone 250mg tablets

Abiraterone (Yonsa, Zytiga)

- For the diagnosis of **Metastatic, High-Risk Castration-Sensitive Prostate Cancer [Zytiga only]**, approve if:
  - One of the following:
    - Prescription is written for generic 250mg tablets
    - All of the following:
      a. Patient is 18 years of age or older
      b. Patient will not receive dual therapy with another androgen receptor inhibitor
      c. The requested agent will be used in combination with prednisone
      d. One of the following:
        i. Patient has had bilateral orchiectomy
        ii. The requested agent will be used in combination with a gonadotropin-releasing hormone (GnRH) analog
      e. There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic abiraterone 250mg tablets

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 2/2024

Abrocitinib (Cibinqo)

Specific Therapeutic Class: *Janus Kinase Inhibitor*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Atopic dermatitis

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Atopic Dermatitis.** approve if:
  - Diagnosis of moderate to severe atopic dermatitis
  - Patient is 18 years of age or older
  - Body surface area (BSA) involvement > 10%
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 high potency topical corticosteroid AND topical calcineurin inhibitor (note: If patient meets approval criteria, a high-potency topical corticosteroid should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use crisaborole (Eucrisa)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dupilumab (Dupixent)
  - Patient has been counseled on increased cardiovascular risks

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- Patient has not experienced an MI or stroke since last review

References: N/A

Last review/revision date: 9/2023

Acalabrutinib (Calquence)

Specific Therapeutic Class: *Antineoplastic Agent, Bruton Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic lymphocytic leukemia
- Small lymphocytic lymphoma
- Mantle cell lymphoma (previously treated)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*: Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma**, approve if:
  - Patient is 18 years of age or older

- For the diagnosis of **Mantle Cell Lymphoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has received at least 1 prior chemotherapy regimen

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Acalabrutinib (Calquence)

References: N/A

Last review/revision date: 2/2022

Acetaminophen-Codeine

Standard/Specific Therapeutic Class: *Narcotic Analgesics*

Formulary Status:

- Formulary
  - Acetaminophen with codeine 120-12 mg/5ml solution (age minimum, 12 years)
  - Acetaminophen with codeine 120-12 mg oral suspension (age minimum, 12 years) (Capital with codeine)
  - Acetaminophen with codeine (Capital with codeine) 300-15 mg tablet (age minimum, 12 years)
  - Acetaminophen with codeine (Tylenol-Codeine #3) 300-30 mg tablet (age minimum, 12 years)
  - Acetaminophen with codeine (Tylenol-Codeine #4) 300-60 mg tablet (age minimum, 12 years)

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are me by one of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

Acetaminophen-Codeine

- For requests for formulary medication over subsequent fill quantity limit, approve if:
  - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
  - Indication of chronic cancer pain
  - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
  - There is documented failure despite compliance to long-acting opiates
  - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 2/2024

Acitretin (Soriatane)

Standard/Specific Therapeutic Class: *Systemic Antipsoriatic Agents, Retinoid-Like Compound*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Plaque psoriasis

Prescribing Restriction

- Quantity Limit*: # 60 per 30 days
- Prescriber restriction: Prescriber must be a Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose
- Prescriber specialty

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Moderate to Severe Plaque Psoriasis**, approve if:
  - Member is 18 years of age or older
  - Prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use topical steroids AND calcipotriene, tazarotene, anthralin, or coal tar OR Failure of cyclosporine, methotrexate or UVB or PUVA therapy
  - The patient and prescriber are participating in Do Your P.A.R.T. program to prevent pregnancy

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 2/2022

Adagrasib (Krazati)

Specific Therapeutic Class: *Antineoplastic Agent, KRAS Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**, approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - There is documentation of a KRAS G12C mutation as detected by an FDA-approved test
  - Patient has received at least 1 prior systemic therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Adalimumab (Humira)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate (NOTE: dose of #4 per 28 days is NOT approvable if methotrexate is already being used in combination with Humira). Suggest Enbrel, Stelara or Taltz, depending on diagnosis, before increasing to weekly Humira.
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose

Adalimumab (Humira)

- Prescriber restriction: rheumatologist, dermatologist, or gastroenterologist (see specific diagnosis in Coverage Criteria)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

Adalimumab (Humira)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a rheumatologist.
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

Adalimumab (Humira)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a rheumatologist or dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a gastroenterologist or rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis

Adalimumab (Humira)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a Gastroenterologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-aacf (Idacio)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-aacf (Idacio)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-aacf (Idacio)

- Patient has diagnosis of juvenile idiopathic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug has been prescribed or is currently being supervised by a Rheumatologist.
- There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-aacf (Idacio)

- Patient is 18 years of age or older
- Diagnosis of psoriatic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a Rheumatologist or Dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks

Adalimumab-aacf (Idacio)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-aaty (Yuflyma)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-aaty (Yuflyma)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-aaty (Yuflyma)

- Patient has diagnosis of juvenile idiopathic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug has been prescribed or is currently being supervised by a Rheumatologist.
- There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-aaty (Yuflyma)

- Patient is 18 years of age or older
- Diagnosis of psoriatic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a Rheumatologist or Dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist

Adalimumab-aaty (Yuflyma)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-adaz (Hyrimoz)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-adaz (Hyrimoz)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-adaz (Hyrimoz)

- Patient has diagnosis of juvenile idiopathic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug has been prescribed or is currently being supervised by a Rheumatologist.
- There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-adaz (Hyrimoz)

- Patient is 18 years of age or older
- Diagnosis of psoriatic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a Rheumatologist or Dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist

Adalimumab-adaz (Hyrimoz)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-adbm (Cyltezo)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-adbm (Cyltezo)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-adbm (Cyltezo)

  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist.
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-adbm (Cyltezo)

  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist

Adalimumab-adbm (Cyltezo)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-afzb (Abrilada)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-afzb (Abrilada)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-afzb (Abrilada)

  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist.
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-afzb (Abrilada)

- Patient is 18 years of age or older
- Diagnosis of psoriatic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a Rheumatologist or Dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist

Adalimumab-afzb (Abrilada)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-aqvh (Yusimry)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-aqvh (Yusimry)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-aqvh (Yusimry)

  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist.
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-aqvh (Yusimry)

- Patient is 18 years of age or older
- Diagnosis of psoriatic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a Rheumatologist or Dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist

Adalimumab-aqvh (Yusimry)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-atto (Amjevita)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-atto (Amjevita)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-atto (Amjevita)

  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist.
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-atto (Amjevita)

  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist

Adalimumab-atto (Amjevita)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-bwwd (Hadlima)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-bwwd (Hadlima)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist.

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  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids

Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

Adalimumab-bwwd (Hadlima)

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 10/2023

Adalimumab-fkjp (Hulio)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-fkjp (Hulio)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-fkjp (Hulio)

- Patient has diagnosis of juvenile idiopathic arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug has been prescribed or is currently being supervised by a Rheumatologist.
- There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-fkjp (Hulio)

  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist

Adalimumab-fkjp (Hulio)

- If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2024

Adalimumab-ryvk (Simlandi)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Hidradenitis Suppurativa
- Uveitis

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
    - #2 per 28 days (1 kit or #2 syringes/vials) OR
    - #4 per 28 days (2 kits or #4 syringes/vials) with documented treatment failure of 40 mg every other week (16 weeks of continuous therapy) AND medical reason for not using methotrexate
  - Juvenile Idiopathic Arthritis
    - #2 per 28 days (1 kit or 2 syringes, 20mg/0.4ml if 15-30kg in weight or 40mg/0.8ml if >=30kg weight)
  - Plaque Psoriasis
    - #4 per 28 days x 1 month (Psoriasis starter package, 4 x 40mg syringes)
    - Then #2 per 28 days (#1 kit/#2 syringes/pens)
  - Crohn's Disease, Ulcerative Colitis
    - 40 g #6 per 28 days x 1 month (Crohn's Disease starter package, contains 6 x 40mg syringes)
    - Then 40 mg #2 per 28 days (#1 kit, #2 syringes/vials)
  - Hidradenitis Suppurativa
    - #4 (160mg) on day 1, then 80mg on day 15
    - Then 40mg weekly (#4 per 28 days)
  - Uveitis
    - 80mg as a single dose followed by 40mg every other week beginning 1 week after initial dose
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Adalimumab-ryvk (Simlandi)

Clinical Information Required for Review:

- Quantity Limit: Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age

Adalimumab-ryvk (Simlandi)

  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist.
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has documented clinical diagnosis of juvenile clinical diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Psoriatic Arthritis**, approve if:

Adalimumab-ryvk (Simlandi)

  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one **oral** DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as **corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as **acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics**
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist
  - If the request is for weekly dosing, there is documentation of trial and failure or inadequate/incomplete response to at least 3 months of dosing once every two weeks

Adalimumab-ryvk (Simlandi)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids**
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

- For diagnosis of **Uveitis**, approve if:
  - Patient is 2 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Patient has a diagnosis of non-infectious intermediate or posterior uveitis or panuveitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or tacrolimus
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 4/2024

Adefovir dipivoxil (Hepsera)

Specific Therapeutic Class: *Antihepadnaviral, Reverse Transcriptase Inhibitor, Nucleotide (Anti-HBV)*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis B Viral Infection (HBV)

Prescribing Restriction:

- Quantity Limit*: #30 tablets per 30 days
- Prescriber restriction: Prescribed by or in consultation with an infectious disease specialist, gastroenterologist, or hepatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatitis B Viral Infection (HBV)**, approve if:
  - Patient is 12 years of age or older
  - Patient is not receiving concurrent tenofovir-containing medications
  - For patients with lamivudine-resistant HBV, requested agent will be used in combination with lamivudine
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use entecavir or tenofovir
  - There is documentation of evidence of viral replication

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is not receiving concurrent tenofovir-containing medications
- Medication is used for appropriate indication and at appropriate dose
- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 3/2023

Afatinib (Gilotrif)

Specific Therapeutic Class: *Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Metastatic non-small cell lung cancer (EGFR mutation-positive)
- Metastatic squamous non-small cell lung cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be oncologist or hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**, approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - There is documentation of non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test
  - Patient does not have documented interstitial lung disease

- For the diagnosis of **Squamous Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - There is documentation of cancer progression after platinum-based chemotherapy
  - Patient does not have documented interstitial lung disease

- For the diagnosis of **Off-Label Indications**, approve if:

Afatinib (Gilotrif)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Age Limit Exception

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- FDA approved indications
- See off-label criteria

Prescribing Restriction:

- Quantity Limit: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- If the PA request is based on an age limit exception required for **patients under 5 years of age,** Approve if:
  - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence

- If the PA request is based on an age limit exception required for **patients under 6 years of age,** Approve if:
  - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence

- If the PA request is based on an age limit exception required for **patients under 9 years of age,** Approve if:
  - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence

- If the PA request is based on an age limit exception required for **patients under 12 years of age,** Approve if:
  - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence

- If the PA request is based on an age limit exception required for **patients under 15 years of age,** Approve if:
  - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence

- If the PA request is based on an age limit exception required for **patients under 16 years of age,** Approve if:
  - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence

Age Limit Exception

- If the PA request is based on an age limit exception required for **patients under 18 years of age,** Approve if:
  - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence

- If the PA request is based on an age limit exception required for **patients under 50 years of age,** Approve if:
  - One of the following:
    - Use of the medication in persons of the patients age is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence for the indication for which it is prescribed confirmed by medical records
    - There is documentation that the patient has a diagnosis for an FDA-approved indication confirmed by medical records

- If the PA request is based on an age limit exception required for **patients over 12 years of age,** Approve if:
  - The patient is unable to take an alternative oral dosage form due to swallowing limitations or requires non-oral enteral administration confirmed by medical records

- If the PA request is based on an age limit exception required for **patients over 35 years of age,** Approve if:
  - The requested agent will not be used for cosmetic purposes (ex: wrinkles)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 7/2023

Alectinib (Alecensa)

Specific Therapeutic Class: *Antineoplastic Agent, Anaplastic Lymphoma Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (NSCLC)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer (NSCLC)**, approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient is Anaplastic Lymphoma Kinase (ALK)-positive confirmed by FDA-approved test
  - The patient does not have severe renal impairment (CrCl <30ml/min) or end stage renal disease

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Alirocumab (Praluent)

Specific Therapeutic Class: *Antilipemic Agent, PCSK9 Inhibitor; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Primary hyperlipidemia
  - Heterozygous Familial Hypercholesterolemia (HeFH)
  - Homozygous Familial Hypercholesterolemia (HoFH)
- Reduction of risk for myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease

Prescribing Restriction:

- Quantity Limit*:
  - 75mg/ml: #2 per 28 days
  - 150mg/ml: #2 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose
- Lipid levels

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Primary Hyperlipidemia**, approve if:
  - Patient is 18 years of age or older*
  - Two fasting lipid panel labs within the past 12 months demonstrate abnormal LDL levels > 100mg/dL
  - Documented claim history or chart notes showing consistent therapy and trial with one high-intensity statin regimen (atorvastatin 40-80mg or rosuvastatin 20-40mg) with inadequate response still requiring additional LDL lowering, or a documented medical reason (e.g., intolerance, hypersensitivity) for not utilizing high-dose statin
  - If request indicates that the patient is “statin intolerant”, documentation was provided including description of the side effects, duration of therapy, “wash out”, re-trial, and then change of agents. Patient should have documentation of trial and failure with documented compliance of at least two statin therapies
  - If ezetimibe is indicated below, it should be tried prior to PCSK9 inhibitor per table below OR there must be documentation of trial and failure with documented compliance, intolerance, contraindication, or inability to use ezetimibe

Alirocumab (Praluent)

- If the patient has Heterozygous Familial Hypercholesterolemia (HeFH) or Homozygous Familial Hypercholesterolemia (HoFH), all of the following are met:
  - Pre-treatment LDL is greater than 190mg/dL AND one of the following:
    a. One of the following:
      i. Family history of myocardial infarction in first-degree relative < 60 years of age
      ii. Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
      iii. Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
      iv. Family history of tendinous xanthoma and/or arcus cornealis in first- or second degree relative
      v. Premature coronary artery disease (<21 years of age)
    b. One of the following:
      i. Family history of myocardial infarction in first-degree relative < 60 years of age
      ii. Functional mutation in LDL, apoB, or PCSK9 gene
      iii. Tendinous xanthoma
      iv. Arcus cornealis before age 45

- For the diagnosis of **Myocardial Infarction, Stroke, and Unstable Angina Requiring Hospitalization in Adults with Established Cardiovascular Disease**, approve if:
  - Two fasting lipid panel labs within the past 12 months demonstrate abnormal LDL levels > 70mg/dL
  - Documented claim history or chart notes showing consistent therapy and trial with one high-intensity statin regimen (atorvastatin 40-80mg or rosuvastatin 20-40mg) with inadequate response still requiring additional LDL lowering, or a documented medical reason (e.g., intolerance, hypersensitivity) for not utilizing high-dose statin
  - If request indicates that the patient is “statin intolerant”, documentation was provided including description of the side effects, duration of therapy, “wash out”, re-trial, and then change of agents. Patient should have documentation of trial and failure with documented compliance of at least two statin therapies
  - If ezetimibe is indicated below, it should be tried prior to PCSK9 inhibitor per table below OR there must be documentation of trial and failure with documented compliance, intolerance, contraindication, or inability to use ezetimibe

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient continues to receive stain and/or ezetimibe at maximally tolerated doses (unless there is appropriately documented trial and failure)
- There is documentation in LDL reduction while on therapy

**Patients aged 12 to 17 will be reviewed on a case-by-case basis*

Alirocumab (Praluent)

Member Age	Co-Morbidities	LDL Level	Treatment Regimen
≥ 21 years old	• Stable Clinical ASCVD • **NO** other co-morbidities	>70-189mg/dL	1. Add EZETIMIBE to current statin therapy first 2. Add PCSK9 inhibitor **OR** replace with PCSK9 inhibitor second
≥ 21 years old	• Clinical ASCVD • **WITH** co-morbidities that increase likelihood of cardiovascular event [Diabetes Mellitus (DM), daily smoker, metabolic syndrome, etc.]	>70-189mg/dL	1. Add EZETIMIBE to current statin therapy first 2. Add PCSK9 inhibitor **OR** replace with PCSK9 inhibitor second
40-75 years old	• Diabetes (DM) and without ASCVD • No diabetes with ≥ 7.5% estimated 10-year risk for ASCVD	70-189mg/dL	1. Add EZETIMIBE to current statin therapy* 2. Add PCSK9 inhibitor **OR** replace with PCSK9 inhibitor second **May also consider bile acid sequestrant*

References: N/A

Last review/revision date: 9/2022

Alitretinoin (Panretin)

Specific Therapeutic Class: *Antineoplastic Agent, Retinoic Acid Derivative*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Kaposi sarcoma cutaneous lesions

Prescribing Restriction:

- Quantity Limit*: #60 grams per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Dermatologist or an HIV Specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Kaposi Sarcoma Cutaneous Lesions**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of cutaneous lesions on the patient with AIDS-related Kaposi's sarcoma
  - Patient is currently on antiviral therapy

References: N/A

Last review/revision date: 2/2022

Alpelisib (Piqray, Vijoyce)

Specific Therapeutic Class: *Antineoplastic Agent, Phosphatidylinositol 3-Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial:
  - Breast Cancer: Indefinite
  - PROS: 6 months
- Continuation:
  - Breast Cancer: N/A
  - PROS: 6 months

Diagnosis Considered for Coverage:

- Breast Cancer (advanced or metastatic)
- PIK3CA-related Overgrowth Spectrum (PROS)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist, Hematologist, Endocrinologist, or genetic specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - Disease is advanced or metastatic
  - Patient is hormone receptor (HR)-positive confirmed by an FDA-approved test
  - Patient is human epidermal growth factor receptor 2 (HER2)-negative confirmed by an FDA-approved test
  - Patient has a PIK3CA mutation confirmed by an FDA-approved test
  - Patient has experienced progression on or after an endocrine-based regimen
  - If the patient is female, they are postmenopausal
  - The requested agent will be used in combination with fulvestrant
  - Prescription is written for Alpelisib (Piqray)

Alpelisib (Piqray, Vijoyce)

- For the diagnosis of **PIK3CA-related Overgrowth Spectrum (PROS)**
  - Patient is 2 years of age or older
  - Patient has a diagnosis of a PROS related condition confirmed by an FDA-approved genetic test
  - Patient has severe manifestations and requires systemic therapy
  - Patient does not have type I diabetes mellitus or uncontrolled type II diabetes mellitus
  - Prescription is written for Alpelisib (Vijoyce)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- If the continuation request is for breast cancer, approve
- If the continuation request is for PROS, all of the following:
  - There is documentation supporting improvement in disease severity from baseline
  - The patent has not experienced unacceptable toxicity while receiving therapy
  - Patient has been compliant with therapy (confirmed via fill history)

References: N/A

Last review/revision date: 9/2023

Ambrisentan (Letairis)

Specific Therapeutic Class: *Endothelin Receptor Antagonists*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary Arterial Hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #30 tablets per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Pulmonary Arterial Hypertension (PAH)** approve if:
  - Patient has a diagnosis of PAH confirmed by RHC
  - There is documentation that the patient has WHO functional class (FC) II or III symptoms
  - The patient and prescriber have met all REMS criteria
  - The patient does not have idiopathic pulmonary fibrosis

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Last review/revision date: 6/2024

Amifampridine (Ruzurgi, Firdapse)

Specific Therapeutic Class: *Cholinergic Agonist; Potassium Channel Blocker*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Lambert-Eaton myasthenic syndrome (LEMS)

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Lambert-Eaton Myasthenic Syndrome (LEMS)**, approve if:
  - Patient has a diagnosis of LEMS confirmed by an FDA-approved test
  - Patient is 6 years of age or older
  - Patient does not have a history of seizures
  - Documentation of a baseline clinical muscle strength assessment (examples may include but are not limited to the Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW))
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use pyridostigmine
  - If the prescription is written for Firdapse, all of the following:
    - Patient is 18 years of age or older
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Ruzurgi

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy as evidenced by clinical muscle strength assessments (examples may include but are not limited to the QMG score, 3TUG test, T25FW test)

References: N/A

Last review/revision date: 2/2022

Amikacin (Arikayce)

Specific Therapeutic Class: *Antibiotic, Aminoglycoside*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Mycobacterium Avium Complex

Prescribing Restriction:

- Quantity Limit*: #30 vials per 30 days
- Prescriber restriction: Prescribed by or in consultation with an infectious disease specialist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Mycobacterium Avium Complex**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of MAC confirmed by an FDA-approved test
  - There is documentation of failure, as evidenced by positive sputum culture, of at least a 6-month trial of a multidrug background regimen therapy at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of at least 3 consecutive negative monthly sputum cultures in the first 6 months of therapy or at least 2 consecutive negative monthly sputum cultures in the last 2 months of therapy

References: N/A

Last review/revision date: 2/2022

Anakinra (Kineret)

Specific Therapeutic Class: *Antirheumatic, Disease Modifying; Interleukin-1 Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Deficiency of interleukin-1 receptor antagonist
- Neonatal-onset multisystem inflammatory disease
- Rheumatoid arthritis

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: Prescriber is a specialist in the area of the patient's requested indication or has consulted with a specialist in the area of the patient's requested indication (e.g., immunologist, pediatrician, rheumatologist)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Deficiency of Interleukin-1 Receptor Antagonist,** approve if:
  - The prescriber is a specialist in the area of the patient's requested indication or has consulted with a specialist in the area of the patient's requested indication (e.g., allergist, autoimmune specialist, immunologist, pediatrician)
  - ONE of the following:
    - The patient is NOT currently being treated with another biologic immunomodulator
    - The patient is currently being treated with another biologic immunomodulator and it will be discontinued prior to starting the requested agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Rilonacept (Arcalyst)
- For the diagnosis of **Neonatal-onset Multisystem Inflammatory Disease,** approve if:
  - The patient has ONE Of the following diagnoses:
    - Cryopyrin Associated Periodic Syndrome (CAPS)
    - Familial Cold Auto-Inflammatory Syndrome (FCAS)
    - Muckle-Wells Syndrome (MWS)
    - Neonatal-onset multisystem inflammatory disorder (NOMID)
  - The prescriber is a specialist in the area of the patient's requested indication or has consulted with a specialist in the area of the patient's requested indication (e.g., allergist, autoimmune specialist, immunologist, pediatrician)
  - ONE of the following:

Anakinra (Kineret)

        - The patient is NOT currently being treated with another biologic immunomodulator
        - The patient is currently being treated with another biologic immunomodulator and it will be discontinued prior to starting the requested agent

- For the diagnosis of **Rheumatoid Arthritis,** approve if:
    - Patient is 18 years of age or older
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed by or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
        - ONE of the following:
            - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
                - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
            - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
        - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e, drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For the diagnosis of **Covid-19,** deny

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
    - The patient has shown clinical improvement with the requested agent (i.e., improvement in serum levels of C-Reactive Protein (CRP), improvement in Serum Amyloid A (SAA), slowing of disease progression, decrease in symptom severity and/or frequency)

References: N/A

Last review/revision date: 9/2023

Apalutamide (Erleada)

Specific Therapeutic Class: *Antineoplastic Agent, Antiandrogen*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prostate cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be oncologist or hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prostate Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic castration-sensitive disease or non-metastatic castration-resistant disease
  - One of the following:
    - Patient is receiving a gonadotropin-releasing hormone (GnRH) analog
    - Patient has had a bilateral orchiectomy
  - Patient will not receive dual therapy with another androgen receptor inhibitor

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Apalutamide (Erleada)

Last review/revision date: 1/2023

Apomorphine (Apokyn, Kynmobi)

Specific Therapeutic Class: *Anti-Parkinson Agent, Dopamine Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Parkinson's Disease

Prescribing Restriction:

- Quantity Limit*:
  - Apomorphine (Apokyn): #90ml per 30 days
  - Apomorphine (Kynmobi): #150 per 30 days
- Prescriber restriction: Prescriber is a Neurologist, or the prescriber has consulted with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Parkinson's Disease**, approve if:
  - Patient is 18 years of age or older
  - The requested agent is prescribed in combination with carbidopa/levodopa
  - The requested agent will be used to treat acute, intermittent hypomobility, "off" episodes (muscle stiffness, slow movements, or difficulty starting movement) associated with advanced Parkinson's disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Rasagiline (Azilect) AND one of the following:
    - Entacapone (Comtan/Stalevo),
    - Ropinirole/ropinirole ER (Requip/Requip XL)
    - Pramipexole/pramipexole ER (Mirapex/Mirapex ER)
    - Neupro (ritigotine)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Safinamide (Xadago)
  - If the request is for Apomorphine (Apokyn): there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Apomorphine (Kynmobi)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improvement in symptoms while using the requested agent

References: N/A

Apomorphine (Apokyn, Kynmobi)

Last review/revision date: 1/2023

Apremilast (Otezla)

Therapeutic Category: *Phosphodiesterase-4 Enzyme Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Plaque psoriasis
- Psoriatic arthritis
- Behçet's disease

Prescribing Restrictions:

- Quantity Limit:
  - Initial: 10 mg on day 1, 10 mg twice daily day 2, 10 mg in morning 20 mg in evening day 3, 20 mg twice daily day 4, 20 mg in morning and 30 mg in evening day 5
  - Maintenance: 30 mg twice daily starting on day 6
- Prescriber restriction: Rheumatologist or Dermatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 6 years of age or older and weighs ≥20kg
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept

Apremilast (Otezla)

(Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), guselkumab (Tremfya), ixekizumab (Taltz), or risankizumab-rzaa (Skyrizi)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), guselkumab (Tremfya), ixekizumab (Taltz), tofacitinib (Xeljanz), tofacitinib ER (Xeljanz XR), Risankizumab-Rzaa (Skyrizi), or Upadacitinib (Rinvoq)

- For diagnosis of **Behçet's Disease**, approve if:
  - Patient has a diagnosis of Bechcet's disease
  - Patient has active oral ulcers
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following: Oral glucocorticoids, colchicine, topical corticosteroids.
  - Requested agent is prescribed by or in consultation with a Rheumatologist or Dermatologist

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 6/2024

Asciminib (Scemblix)

Specific Therapeutic Class: *Antineoplastic Agent, BCR-ABL Tyrosine Kinase Inhibitor,, STAMP Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic myeloid leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be oncologist or hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Myeloid Leukemia,** approve if:
  - Patient is 18 year of age or older
  - Patient is in the chronic phase
  - Patient is Philadelphia chromosome-positive (Ph+) confirmed by and FDA-approved test
  - Patient has documented trial and failure with Imatinib
  - One of the following
    - Patient has a T315I mutation confirmed by an FDA-approved test
    - Patient has previously received at least one other tyrosine kinase inhibitor (in addition to imatinib)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Asciminib (Scemblix)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 2/2022

Asfotase Alfa (Strensiq)

Specific Therapeutic Class: *Enzyme*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Perinatal/infantile or juvenile-onset hypophosphatasia (HPP)

Prescribing Restriction:

- Quantity Limit*: A quantity sufficient for a 30 day supply based on prescribed dose and frequency of administration
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Perinatal/Infantile or Juvenile-Onset Hypophosphatasia (HPP)**, approve if:
  - The patient was ≤ 18 years of age at onset
  - The patient has/had clinical manifestations consistent with hypophosphatasia at the age of onset prior to age 18 (e.g., vitamin B6- dependent seizures, skeletal abnormalities: such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, “failure to thrive”)
  - The patient has/had radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, alveolar bone loss, craniosynostosis)
  - An FDA-approved molecular genetic test has been completed confirming mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP)
  - Reduced activity of unfractionated serum alkaline phosphatase (ALP) in the absence of bisphosphonate therapy (i.e., below the normal lab reference range for age and sex)
  - Patient has one of the following:
    - Elevated urine concentration of phosphoethanolamine (PEA)
    - Elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test
    - Elevated urinary inorganic pyrophosphate (PPi)
  - The patient does not have any FDA labeled contraindication(s) to the requested agent
  - The prescriber has provided the patient’s weight
  - The requested quantity is within FDA labeled dosing (based on patient’s weight)
  - The patient has a documented baseline ophthalmology exam and renal ultrasound with planned periodical monitoring throughout treatment

Asfotase Alfa (Strensiq)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- The patient has shown clinical improvement with the requested agent as evidenced by an improvement and/or stabilization (upon subsequent renewals) respiratory status, growth, or radiographic findings from baseline [documentation from the medical record is required to be submitted]
- The prescriber has provided the patient's weight
- The requested quantity is within FDA labeled dosing (based on patient's weight)

References: N/A

Last review/revision date: 2/2022

Atogepant (Qulipta)

Specific Therapeutic Class: *Antimigraine Agent; Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Prevention of episodic migraines
- Prevention of chronic migraines

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Prevention of Episodic Migraines,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to us at least 2 injectable CGRPs

- For the diagnosis of **Prevention of Chronic Migraines,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to us at least 2 injectable CGRPs

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 8/2023

Avacopan (Tavneos)

Specific Therapeutic Class: *Complement Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Antineutrophil cytoplasmic autoantibody-associated vasculitis

Prescribing Restriction:

- Quantity Limit*: #180 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Antineutrophil Cytoplasmic Autoantibody-Associated Vasculitis**, approve if:
  - Patient has a diagnosis of antineutrophil cytoplasmic autoantibody-associated vasculitis confirmed by an FDA-approved test
  - Patient has granulomatosis with polyangiitis or microscopic polyangiitis
  - Patient is positive for anti-PR3 or anti-MPO confirmed by an FDA-approved test
  - Patient meets at least one of the following on the Birmingham Vasculitis Activity Score (BVAS):
    - 1 major item
    - 3 non-major items
    - Proteinuria AND hematuria
  - Patient does not currently require dialysis and has an eGFR greater than or equal to 15ml/min/1.72m^2
  - Patient is currently receiving standard therapy with glucocorticoids and either cyclophosphamide or rituximab

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- One of the following:
  - Patient has improved or sustained renal function from baseline
  - Patient has had a decrease in glucocorticoid use from baseline

References: N/A

Last review/revision date: 9/2022

Avapritinib (Ayvakit)

Specific Therapeutic Class: *Antineoplastic Agent, KIT Inhibitor, PDGFR-alpha Blocker; Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Gastrointestinal stromal tumor (unresectable or metastatic)
- Systemic mastocytosis, advanced
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Gastrointestinal Stromal Tumor (GIST),** approve if:
  - Patient is 18 years of age or older
  - Patient has unresectable, recurrent, or metastatic disease
  - Patient is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use imatinib OR sunitinib

- For the diagnosis of **Advanced Systemic Mastocytosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)
  - Patient has a platelet count ≥ 50 x 109/L

- For the diagnosis of **Off-Label Indications**, approve if:

Avapritinib (Ayvakit)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Avatrombopag (Doptelet)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent; Thrombopoietic Agent; Thrombopoietin Receptor Agonist*

Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Chronic immune thrombocytopenia
- Chronic liver disease-associated thrombocytopenia

Prescribing Restriction:

- Quantity Limit*: 40mg per day
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Immune Thrombocytopenia**, approve if:
  - Patient is 18 years of age or older
  - Platelet level < 50,000 mm^3
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ONE of the following: glucocorticoids, intravenous immune globulin (IVIG), rituximab (Rituxan) if appropriate) or splenectomy

- For the diagnosis of **Chronic Liver Disease-Associated Thrombocytopenia**, approve if:
  - Patient is 18 years of age or older
  - Platelet level < 50,000 mm^3
  - Patient is undergoing a scheduled medical or dental procedure within the next 30 days

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2021

Axitinib (Inlyta)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Renal cell carcinoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis & medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Renal Cell Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE prior first line systemic therapy (ex: nivolumab plus ipilimumab, nivolumab plus cabozantinib, etc)
    - Requested use is for first line therapy in combination with pembrolizumab (Keytruda)
    - Requested use is for first line therapy in combination with avelumab (Bavencio)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Axitinib (Inlyta)

References: N/A

Last review/revision date: 2/2022

Azacitidine (Onureg)

Specific Therapeutic Class: *Antineoplastic Agent, Antimetabolite, DNA Methylation Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia**, approve if:
  - Patient is 18 years of age or older
  - Request is for oral tablet
  - The patient has received previous treatment with an intensive induction chemotherapy regimen
  - The request is for use in post-remission maintenance therapy
  - Patient is not able to complete intensive curative therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Azacitidine (Onureg)

Last review/revision date: 2/2022

Aztreonam (Cayston)

Specific Therapeutic Class: *Antibiotic, Monobactam*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cystic Fibrosis

Prescribing Restriction:

- Quantity Limit*: #84 ml per 56 days (75 mg/ml TID; 28 days on, 28 days off therapy)
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Cystic Fibrosis**, approve if:
  - Patient is 3 months of age or older
  - The patient has a diagnosis of cystic fibrosis confirmed by an FDA-approved test
  - The patient has documented colonization/infection with *P. aeruginosa* confirmed by an FDA-approved test
  - The medication is being prescribed at a dose that is within FDA approved guidelines

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2022

Baricitinib (Olumiant)

Therapeutic Category: *Antirheumatic Miscellaneous; Antirheumatic, Disease Modifying; Janus Kinase Inhibitor*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Alopecia areata (Not Covered)
- Covid-19 (Not Covered)

Prescribing Restrictions:

- Quantity Limit: 30 tablets per 30 days
- Prescriber restriction: Rheumatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - Patient has been counseled on increased cardiovascular risks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)

Baricitinib (Olumiant)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use or Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Alopecia Areata,** deny (not covered)

- For diagnosis of **Covid-19,** deny (not covered)

III. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- Patient has not experienced an MI or stroke since last review

References: N/A

Last review/revision date: 7/2023

Bedaquiline (Sirturo)

Specific Therapeutic Class: *Antitubercular Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 9 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Pulmonary Tuberculosis

Prescribing Restriction:

- Quantity Limit*:
  - Initial Fill: #56 per 14 days
  - All subsequent fills: #24 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pulmonary Tuberculosis**, approve if:
  - Patient is at least 5 years of age
  - Patient weighs at least 15kg
  - Diagnosis is laboratory confirmed pulmonary multi-drug resistant (MDR) tuberculosis (TB) with an isolate showing genotypic or phenotypic resistance to both INH and RIF
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 other anti-infectives (fluoroquinolones, linezolid, capreomycin/amikacin, etc)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 3/2022

Belimumab (Benlysta)

Specific Therapeutic Class: *Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Lupus nephritis
- Systemic lupus erythematosus

Prescribing Restriction:

- Quantity Limit*:
  - Initial: #8 per 28 days
  - All subsequent fills: #4 per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Nephrologist or Rheumatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Lupus Nephritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of lupus nephritis confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 1 of the following:
    - Cyclophosphamide + glucocorticoids
    - Mycophenolate + glucocorticoids
  - The requested agent will be used in combination glucocorticoids + either mycophenolate or cyclophosphamide

- For the diagnosis of **Systemic Lupus Erythematosus**, approve if:
  - Patient is 5 years of age or older
  - The patient has a history of positive antinuclear antibody (ANA) and/or positive anti-dsDNA results
  - The patient has a history of 3 other SLE diagnostic criteria (i.e., malar rash, discoid rash, photosensitivity, oral ulcers, nonerosive arthritis, serositis (e.g., pleuritis/pericarditis), renal disorder (e.g., persistent proteinuria >0.5 grams/day or cellular casts), hematologic disorder (e.g., hemolytic anemia with reticulocytosis, leukopenia, lymphopenia, or thrombocytopenia), and/or immunologic disorder (e.g., positive finding of antiphospholipid antibodies or anti-Sm antibodies)
  - ONE of the following:

Belimumab (Benlysta)

- BOTH of the following:
  a. The patient has tried and had an inadequate response to TWO of the following classes: corticosteroids, antimalarials (e.g., hydroxychloroquine, chloroquine), nonsteroidal anti-inflammatory drugs (NSAIDS), aspirin, and/or immunosuppressives (e.g., azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate A
  b. The patient is currently being treated with at least ONE of the following classes: corticosteroids, antimalarials (e.g., hydroxychloroquine, chloroquine), nonsteroidal anti-inflammatory drugs (NSAIDS), aspirin, and/or immunosuppressives (e.g., azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate) within the past 90 days
- The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL of the following classes: corticosteroids, antimalarials (e.g., hydroxychloroquine, chloroquine), nonsteroidal anti-inflammatory drugs (NSAIDS), aspirin, and/or immunosuppressives (e.g., azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate)

- The patient does NOT have severe active central nervous system lupus
- ONE of the following:
  - The patient is NOT currently being treated with another biologic agent OR intravenous cyclophosphamide and has not received either within the past 30 days
  - The patient is currently being treated with another biologic agent or intravenous cyclophosphamide within the past 30 days AND will discontinue prior to starting the requested agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented improvement from baseline or last review defined as positive changes in renal function, hypertension, proteinuria, and/or SLE disease markers
- There is documentation of ongoing need for therapy

References: N/A

Last review/revision date: 3/2022

Belumosudil (Rezurock)

Standard/Specific Therapeutic Class: *ROCK2 Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Re-authorization: 12 months

Diagnosis Considered for Coverage:

- Chronic Graft-versus-host disease
- Other diagnoses: see off-label criteria

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information required for Review:

- Diagnosis
- Previous and current therapy
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Graft-Versus-Host Disease** approve if:
  - Patient is 12 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to at least two prior guideline-directed lines of therapy

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 9/2023

Belzutifan (Welireg)

Specific Therapeutic Class: *Antineoplastic Agent, HIF-2alpha Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Von Hippel-Lindau disease
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Von Hippel-Lindau Disease**, approve if:
  - Patient is 18 years of age or older
  - Patient requires treatment of associated renal cell carcinoma, CNS hemangioblastomas, or pancreatic neuroendocrine tumors
  - Patient does not require immediate surgery
  - If the patient is a female of reproductive potential, there is documentation of a negative pregnancy test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Belzutifan (Welireg)

Last review/revision date: 9/2023

Benralizumab (Fasenra)

Specific Therapeutic Class: *Interleukin-5 Receptor Antagonist; Monoclonal Antibody, Anti-Asthmatic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Asthma

Prescribing Restriction:

- Quantity Limit*:
  - First 3 months: #1 per 28 days
  - Continuation after 3 months: #1 per 56 days
- Prescriber restriction: Prescribed by or in consultation with a pulmonologist, immunologist, or allergist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Asthma**, approve if:
  - Patient is 6 years of age or older
  - Patient has an absolute blood eosinophil count ≥150 cells/mcL within the past 3 months
  - Patient has experienced ≥ 2 exacerbations with in the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (ICS) plus either a long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindication/intolerance):
    - Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
    - Urgent care visit or hospital admission
    - Intubation
  - The requested agent is prescribed concomitantly with an ICS plus either a LABA or LTRA

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented adherence to asthma controller therapy that includes an ICS plus either an LABA or LTRA
- Patient is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline; reduction in the use of rescue therapy)

References: N/A

Last review/revision date: 6/2024

Berotralstat (Orladeyo)

Specific Therapeutic Class: *Kallikrein Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Hereditary angioedema

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: Prescribed by or in consultation with an allergy specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hereditary Angioedema**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of hereditary angioedema confirmed by an FDA-approved test
  - The requested agent will be used for prophylaxis of HAE attacks
  - Documentation of trial and failure with documented compliance, contraindication to, or inability to use danazol
  - Documentation of at least one HAE attack per month
  - The requested agent will not be used in combination with other agents for the prevention of HAE attacks

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has a documented response to therapy (reduction in HAE attacks)

References: N/A

Last review/revision date: 3/2022

Betaine (Cystadane)

Specific Therapeutic Class: *Homocystinuria, Treatment Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Homocystinuria

Prescribing Restriction:

- Quantity Limit*: 540 grams per 30 days
- Prescriber restriction: Prescribed by or in consultation with metabolic or genetic disease specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Homocystinuria**, approve if:
  - Patient's diagnosis is confirmed by one of the following:
    - Cystathionine beta-synthase (CBS) deficiency
    - 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
    - Cobalamin cofactor metabolism (cbl) defect

References: N/A

Last review/revision date: 3/2022

Bexarotene (Targretin)

Specific Therapeutic Class: *Antineoplastic Agent, Retinoic Acid Derivative*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cutaneous T-cell lymphoma (refractory)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cutaneous T-Cell Lymphoma**, approve if:
  - Patient is 18 years of age or older
  - If the patient is female, there is documentation of a negative pregnancy test within 1 week prior to starting therapy
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE prior systemic therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Bimekizumab-bkzx (Bimzelx)

Therapeutic Category: *Anti-interleukin 17-Receptor Antibody; Antipsoriatic Agent; Monoclonal Antibody*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Plaque psoriasis

Prescribing Restrictions:

- Quantity Limit:
  - Initial: 320 mg at week 0, 4, 8, 12, 16
  - Maintenance 320 mg be every 8 weeks
- Prescriber restriction: Dermatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Plaque Psoriasis,** approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to pre-existing disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried

Bimekizumab-bkzx (Bimzelx)

and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), or risankizumab-rzaa (Skyrizi)

III. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 1/2024

Binimetinib (Mektovi)

Specific Therapeutic Class: *Antineoplastic Agent, MEK Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Melanoma (unresectable or metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Melanoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has unresectable or metastatic disease
  - Patient has a BRAF V600E or V600K mutation confirmed by an FDA-approved test
  - The requested agent will be used in combination with encorafenib (Braftovi)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 3/2022

Blood Glucose Meters (Non-Formulary)

Standard/Specific Therapeutic Class: *Medical Supplies/Diabetic Supplies*

Formulary Status:

- Formulary:
  - One Touch
- Not Covered:
  - All other blood glucose meters

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes

Prescribing Restriction:

- Quantity Limit*: 1 unit per year (365 days)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

**If patient meets PA criteria a tier override will be provided*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- Approve only if patient is using an insulin pump that is incompatible with One Touch blood glucose meters confirmed by pump manufacturer

References: N/A

Last review/revision date: 6/2023

Blood Glucose Monitoring Test Strips (Non-Formulary)

Standard/Specific Therapeutic Class: *Medical Supplies/Diabetic Supplies*

Formulary Status:

- Formulary:
  - One Touch

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes Mellitus type 1 or 2

Clinical Information Required for Review

- Diagnosis
- Previous medications

Prescribing Restriction

- Quantity Limit*:
  - Test strips: #5 strips per day (#150/30 days)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

**If patient meets PA criteria a tier override will be provided*

Coverage Criteria:

I. Initiation of Therapy:

- For One Touch, if over formulary quantity limit approve if:
  - If over formulary quantity limit, approve if there is medical need for glucose monitoring more frequent than 4 times daily, or 8 times daily in the case of gestational diabetes. E.g., frequent hospitalizations, incidents of hypoglycemia, DKA hospitalizations etc.

- For all other strips, approve if:
  - There is documented trial and failure with One Touch branded test strips manufactured by LifeScan OR If the patient is stabilized on an insulin pump where it is medically necessary to use a nonpreferred diabetic test strip (a tier override will also be provided)
  - If over formulary quantity limit, approve if there is medical need for glucose monitoring more frequent than 4 times daily, or 8 times daily in the case of gestational diabetes. E.g., frequent hospitalizations, incidents of hypoglycemia, DKA hospitalizations etc.

References: N/A

Last review/revision date: 7/2023

Bosentan (Tracleer)

Specific Therapeutic Class: *Endothelin Receptor Antagonist; Vasodilator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary Arterial Hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #60 tablets per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous and current therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Pulmonary Arterial Hypertension (PAH),** approve if:
     - Patient has a diagnosis of PAH confirmed by RHC
     - There is documentation that the patient has WHO functional class (FC) II or III symptoms
     - The patient and prescriber have met all REMS criteria

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Last review/revision date: 6/2024

Bosutinib (Bosulif)

Specific Therapeutic Class: *Antineoplastic Agent, BCR-ABL Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic myeloid leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Myeloid Leukemia**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Patient has newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia confirmed by an FDA-approved test
    - Patient has chronic phase Ph+ chronic myelogenous leukemia AND there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least one tyrosine kinase inhibitor (TKI)
    - Patient has accelerated phase Ph+ chronic myelogenous leukemia confirmed by an FDA-approved test
    - Patient has blast phase Ph+ chronic myelogenous leukemia confirmed by an FDA-approved test
  - Diagnosis has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing prior to initiation of therapy

- For the diagnosis of **Off-Label Indications**, approve if:

Bosutinib (Bosulif)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 4/2022

Brigatinib (Alunbrig)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Anaplastic Lymphoma Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient is anaplastic lymphoma kinase (ALK)-positive confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Brodalumab (Siliq)

Therapeutic Category: *Anti-interleukin 17-Receptor Antibody; Antipsoriatic Agent; Monoclonal Antibody*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Plaque psoriasis

Prescribing Restrictions:

- Quantity Limit:
  - Initial: 210 mg at week 0, 1, and 2
  - Maintenance 210 mg be every 2 weeks
- Prescriber restriction: Dermatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Plaque Psoriasis,** approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to pre-existing disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried

Brodalumab (Siliq)

and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), or risankizumab-rzaa (Skyrizi)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 1/2024

Budesonide (Eohilia)

Specific Therapeutic Class: *Corticosteroid, Systemic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Eosinophilic Esophagitis

Prescribing Restriction:

- Quantity Limit*: 600ml per 30 days
- Prescriber Restriction: Prescribed by or in consultation with an Allergist or Gastroenterologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Eosinophilic Esophagitis**, approve if:
  - Patient is 11 years of age or older
  - Patient has eosinophil-predominant inflammation confirmed by esophageal biopsy
  - Patient has a peak value of ≥15 eosinophils per high power field (HPF) (or 60 eosinophils per mm^2) confirmed by esophageal biopsy
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to at least 3 months of lifestyle modification including elimination of food antigens that initiate the inflammatory process
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 1 oral PPI
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least one formulary inhaled corticosteroid

References: N/A

Last review/revision date: 6/2024

Budesonide (Tarpeyo)

Specific Therapeutic Class: *Corticosteroid, Systemic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 9 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Primary immunoglobulin A nephropathy (IgAN)

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Nephrologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Primary Immunoglobulin A Nephropathy (IgAN)**, approve if:
  - Patient has primary immunoglobulin A nephropathy (IgAN) confirmed by biopsy
  - Patient has a baseline eGFR ≥35 mL/min/1.73 m^2
  - Patient has baseline proteinuria defined as either ≥1 gram of protein/day or UPCR ≥0.8 g/g
  - Patient is at risk for disease progression defined by a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g
  - Patient has been taking an ACE-inhibitor or ARB at maximally tolerated doses for at least 3 months and will continue to take while receiving the requested agent
  - There is documentation that the patient has received at least 2 months of oral glucocorticoid therapy within the last 12 months

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Prescriber has submitted justification for the need of ongoing therapy
- There is documentation of improvement in proteinuria from baseline
- There is documentation that eGFR has stabilized or improved from baseline

References: N/A

Last review/revision date: 01/2023

Buprenorphine (Subutex)

Specific Therapeutic Class: *Analgesic, Opioid; Analgesic, Opioid Partial Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Opioid Dependence or Opioid Addiction (requests for the diagnosis of pain will be denied)

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Physician meets all qualifications to prescribe buprenorphine/naloxone (Federal, State, and Local)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Opioid Dependence or Opioid Addiction**, approve if:
     - Patient is diagnosed with opioid dependence and/or opioid addiction (requests for the diagnosis of pain will be denied)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing therapy

References: N/A

Last review/revision date: 1/2023

Buprenorphine-Naloxone (Bunavail, Suboxone, Zubsolv)

Specific Therapeutic Class: *Analgesic, Opioid; Analgesic, Opioid Partial Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Opioid Dependence or Opioid Addiction (requests for the diagnosis of pain will be denied)

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Physician meets all qualifications to prescribe buprenorphine/naloxone (Federal, State, and Local)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Opioid Dependence or Opioid Addiction**, approve if:
  - Patient is diagnosed with opioid dependence and/or opioid addiction (requests for the diagnosis of pain will be denied)
  - For requests for buprenorphine/naloxone (Zubsolv, Bunavail), there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: generic buprenorphine/naloxone sublingual tablets, buprenorphine sublingual tablet, or Suboxone

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Burosumab-Twza (Crysvita)

Specific Therapeutic Class: *Anti-FGF23 Monoclonal Antibody; Antineoplastic Agent, Monoclonal Antibody; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Osteomalacia, tumor-induced
- X-linked hypophosphatemia

Prescribing Restriction:

- Quantity Limit*:
  - Osteomalacia, tumor-induced: #6 per 28 days
  - X-linked hypophosphatemia: #3 per 28 days
- Prescriber restriction: Prescribed by or in consultation with an Oncologist, Endocrinologist, or metabolic disease specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Osteomalacia**, approve if:
  - Patient is 2 years of age or older
  - Patient has fibroblast growth factor 23 (FGF23)-related hypophosphatemia confirmed by an FDA-approved test
  - Patient has a phosphaturic mesenchymal tumor confirmed by and FDA-approved test
  - The patient's tumor cannot be curatively resected or localized
  - There is documentation of current (within the last 30 days) serum phosphorus level below the reference range for age and gender (use laboratory-specific reference ranges if available)
  - Patient has not received oral phosphate and/or active vitamin D analogs for at least 1 week

- For the diagnosis of **X-linked Hypophosphatemia**, approve if:
  - Patient is 6 months of age or older
  - Diagnosis of XLH confirmed by one of the following:
    - DNA testing confirms the presence of mutations in the PHEX gene
    - Elevated serum fibroblast growth factor 23 (FGF23) levels
  - There is documentation of current (within the last 30 days) serum phosphorus level below the reference range for age and gender (use laboratory-specific reference ranges if available)

Burosumab-Twza (Crysvita)

- There is documentation of the presence of clinical signs and symptoms of the disease (e.g., rickets, growth impairment, musculoskeletal pain, bone fractures)
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use calcitriol (Rocaltrol) with an oral phosphate agent (K-Phos, K-Phos Neutra)
- Patient has not received oral phosphate and/or active vitamin D analogs for at least 1 week

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy as evidenced by both of the following:
  - An increase in serum phosphorus levels from baseline and/or maintenance within the normal range for age and gender, not to exceed the upper limit of that normal range (use laboratory-specific reference ranges if available)
  - A positive clinical response including any of the following: enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain

References: N/A

Last review/revision date: 4/2022

Busulfan (Myleran)

Specific Therapeutic Class: *Antineoplastic Agent, Alkylating Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic myeloid leukemia

Prescribing Restriction:

- Quantity Limit*: Authorized quantity sufficient for a 30 day supply
- Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Myeloid Leukemia**, approve if:
  - Diagnosis is confirmed by an FDA-approved test
  - The requested agent will be used as palliative treatment

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2022

Butorphanol (Stadol NS)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status: Non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Acute pain (moderate to severe) or migraine
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*: #1 unit/30 days
- Prescriber restriction: Migraine specialist, Neurologist, or pain management specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Dose
- Previous therapy
- Prescriber specialty

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Acute Pain (moderate to severe) or Migraine**, approve if:
  - There is documentation of trial and failure with documented compliance with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **2 or more short acting opioids**
  - Patient is followed by a migraine specialist, neurologist, or pain management specialist

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References:

Last review/revision date: 1/2023

C1 Inhibitor (Haegarda)

Specific Therapeutic Class: *Blood Product Derivative; C1 Esterase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Hereditary angioedema

Prescribing Restriction:

- Quantity Limit*: #16 vials per 28 days
- Prescriber restriction: Prescribed by or in consultation with an allergy specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hereditary Angioedema**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of hereditary angioedema confirmed by an FDA-approved test
  - The requested agent will be used for prophylaxis of HAE attacks
  - Documentation of trial and failure with documented compliance, contraindication to, or inability to use danazol
  - Documentation of patient's weight and quantity/dose requested
  - Documentation of at least one HAE attack per month
  - The requested agent will not be used in combination with other agents for the prevention of HAE attacks

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has a documented response to therapy (reduction in HAE attacks)

References: N/A

Last review/revision date: 3/2022

Cabozantinib (Cabometyx, Cometriq)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatocellular carcinoma, advanced (Cabometyx)
- Renal cell carcinoma, advanced (Cabometyx)
- Thyroid cancer, differentiated (Cabometyx)
- Thyroid cancer, medullary (Cometriq)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatocellular Carcinoma (Cabometyx only),** approve if:
  - Patient is 18 years of age or older
  - Patient has advanced or metastatic disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sorafenib (Nexavar)

- For the diagnosis of **Renal Cell Carcinoma (Cabometyx only)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sunitinib

- For the diagnosis of **Differentiated Thyroid Cancer (Cabometyx only),** approve if:

Cabozantinib (Cabometyx, Cometriq)

- Patient is 12 years of age or older
- Patient has locally advanced or metastatic disease
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use VEGFR-targeted therapy
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use radioactive iodine therapy

- For the diagnosis of **Medullary Thyroid Cancer (Cometriq only),** approve if:
  - Patient is 18 years of age or older
  - Patient has progressive or metastatic disease

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 4/2022

Calcifediol ER (Rayaldee)

Specific Therapeutic Class: *Vitamin D Analog*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Secondary hyperparathyroidism

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Secondary Hyperparathyroidism,** approve if:
  - Patient is 18 years of age or older
  - Patient has stage 3 or 4 chronic kidney disease defined by eGFR of 15-59 mL/min
  - Patient has a serum total 25-hydroxyvitamin D level is less than 30 ng/mL
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ergocalciferol AND cholecalciferol

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy (suspend dosing if intact PTH is persistently abnormally low, serum calcium is consistently above the normal range or serum 25-hydroxyvitamin D is consistently above 100 ng/mL)

References: N/A

Last review/revision date: 4/2022

Canakinumab (Ilaris)

Specific Therapeutic Class: *Interleukin-1 Beta Inhibitor; Interleukin-1 Inhibitor; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Adult-onset Still's disease
- Periodic fever syndromes
- Systemic juvenile idiopathic arthritis

Prescribing Restriction:

- Quantity Limit*: #2 per 28 days
- Prescriber restriction: prescriber is a specialist in the area of the patient's requested indication or has consulted with a specialist in the area of the patient's requested indication (e.g., allergist, autoimmune specialist, immunologist, pediatrician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Adult-Onset Still's Disease**, approve if:
  - Patient is 18 years of age or older
  - Drug has been prescribed or is currently being supervised by a rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glucocorticoids and methotrexate

- For the diagnosis of **Periodic Fever Syndromes**, approve if:
  - Patient has one of the following:
    - Cryopyrin Associated Periodic Syndrome (CAPS)
    - Familial Cold Auto-Inflammatory Syndrome (FCAS)
    - Muckle-Wells Syndrome (MWS)
    - Familial Mediterranean Fever (FMF) AND one of the following:
      a. The patient has tried and had an inadequate response to colchicine for at least 6 months
      b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to colchicine
    - Tumor necrosis factor receptor associated periodic syndrome
    - Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency
  - ONE of the following:

Canakinumab (Ilaris)

        - The patient is NOT currently being treated with another biologic immunomodulator
        - The patient is currently being treated with another biologic immunomodulator and it will be discontinued prior to starting the requested agent
    - The patient does NOT have any FDA labeled contraindication(s) to the requested agent

- For the diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
    - Patient is between 2 and 17 years of age
    - Patient has documented clinical diagnosis of juvenile idiopathic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- The patient has shown clinical improvement with the requested agent (i.e., improvement in serum levels of C-Reactive Protein (CRP), improvement in Serum Amyloid A (SAA), slowing of disease progression, decrease in symptom severity and/or frequency)

References: N/A

Last review/revision date: 7/2023

Cannabidiol (Epidiolex)

Specific Therapeutic Class: *Anticonvulsant; Cannabinoid*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex

Prescribing Restriction:

- Quantity Limit*: A quantity sufficient for a 30 day supply
- Prescriber restriction: Prescribed by or in consultation with a Neurologist or Pediatrician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Seizures**, approve if:
  - The patient has a diagnosis of ONE of the following:
    - Seizure associated with Lennox-Gastaut syndrome and the requested agent will not be used as monotherapy for seizure management
    - Seizure associated with Dravet syndrome and the requested agent will not be used as monotherapy for seizure management
    - Seizures associated with tuberous sclerosis complex and the requested agent will not be used as monotherapy for seizure management
  - The patient is 1 years of age or greater
  - The patient's medication history includes the use of an anticonvulsant in the past 90 days
  - The prescriber has provided the patient's weight
  - The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improvement in seizure activity

References: N/A

Last review/revision date: 4/2022

Cantharidin (Ycanth)

Specific Therapeutic Class: *Keratolytic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 weeks
- Continuation: 12 weeks

Diagnosis Considered for Coverage:

- Molluscum contagiosum

Prescribing Restriction:

- Quantity Limit*: #2 per 21 days
- Prescriber restriction: Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Molluscum Contagiosum,** approve if:
  - Patient is 2 years of age or older
  - The patient has a diagnosis of Molluscum Contagiosum confirmed by an FDA-approved test
  - The patient is experiencing itching or pain, has a concomitant bacterial infection, or has concomitant AD, or there is concern for contagion (e.g. other siblings, daycare)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation submitted to support the need for continued therapy despite completing 4 treatment cycles
- There is published clinical evidence provided to support use of the requested agent beyond 4 treatment cycles

References: N/A

Last review/revision date: 9/2023

Capivasertib (Truqap)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, AKT Inhibitor, Serine/Threonine Kinase AKT Inhibitor*

Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer, locally advanced or metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **breast cancer,** approve if:
  - Patient has a diagnosis of breast cancer confirmed by an FDA-approved test
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient is HR positive and HER2 negative confirmed by an FDA-approved test
  - Patient has one or more PIK3CA/AKT1/PTEN alterations confirmed by an FDA-approved test
  - Patient has experienced disease progression following at least one line of endocrine therapy in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy
  - The requested agent will be given in combination with fulvestrant as subsequent therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Capivasertib (Truqap)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2024

Capmatinib (Tabrecta)

Specific Therapeutic Class: *Antineoplastic Agent, MET Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - Disease is recurrent, advanced, or metastatic
  - The tumor(s) is/are mesenchymal-epithelial transition (MET) exon 14 skipping positive confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Carglumic Acid (Carbaglu)

Specific Therapeutic Class: *Antidote; Metabolic Alkalosis Agent; Urea Cycle Disorder (UCD) Treatment Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Hyperammonemia

Prescribing Restriction:

- Quantity Limit*: Quantity sufficient for a 30 day supply
- Prescriber restriction: Prescribed by or in consultation with a physician experienced in treating metabolic disorders.

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hyperammonemia**, approve if:
  - One of the following
    - Patient has Hyperammonemia associated with N-acetylglutamate synthase deficiency confirmed by an FDA-approved test
    - Patient has Hyperammonemia associated with propionic acidemia or methylmalonic acidemia confirmed by an FDA-approved test

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 4/2022

Cenegermin-BKBJ (Oxervate)

Specific Therapeutic Class: *Recombinant Human Nerve Growth Factor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Neurotrophic keratitis

Prescribing Restriction:

- Quantity Limit*: #28 per 30 days
- Prescriber restriction: Prescribed by or in consultation with an ophthalmologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Neurotrophic Keratitis**, approve if:
  - Patient is 2 years of age or older
  - Patient has a diagnosis of Neurotrophic keratitis confirmed by an FDA-approved test

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy

References: N/A

Last review/revision date: 4/2022

Ceritinib (Zykadia)

Specific Therapeutic Class: *Antineoplastic Agent, Anaplastic Lymphoma Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - Disease is metastatic or recurrent
  - Patient is lymphoma kinase (ALK)-positive confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Certolizumab (Cimzia)

Therapeutic Category: *Antirheumatic, Disease Modifying; Gastrointestinal Agent, Miscellaneous; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Plaque psoriasis
- Psoriatic arthritis
- Crohn's disease
- Axial spondyloarthritis

Prescribing Restrictions:

- Quantity Limit:
  - Ankylosing Spondylitis, axial spondyloarthritis
    - Initial: #3 per 28 days (400 mg weeks 0, 2, 4; dosed with starter kit of 3 sets of 2 syringes 200 ml each)
    - Maintenance: #1 per 28 days (200 mg every 2 weeks or 400 mg every 4 weeks; dosed with 1 set of 2 vials or 2 syringes 200 mg each)
  - Crohn's Disease
    - Initial: #3 per 28 days (400 mg at weeks, 0, 2 and 4)
    - Maintenance: #2 per 28 days (400 mg every 28 days)
  - Plaque psoriasis
    - #2 per 28 days (400 mg every 28 days)
    - If ≤90kg:
      - Initial: #3 per 28 days (400 mg at weeks, 0, 2 and 4)
      - Maintenance: #2 per 28 days (400 mg every 28 days)
  - Psoriatic Arthritis & Rheumatoid Arthritis
    - Initial: #3 per 28 days (400 mg at weeks, 0, 2 and 4)
    - Maintenance: 200 mg (#1) every other week or 400 mg (#2) every 28 days
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older

Certolizumab (Cimzia)

- Patient has diagnosis of moderate to severe rheumatoid arthritis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug has been prescribed by or is currently being supervised by a Rheumatologist
- There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
- ONE of the following:
  - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
    - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e, drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following alternatives: etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), ixekizumab (Taltz), or secukinumab (Cosentyx)

- For diagnosis of **Axial Spondyloarthritis**, approve if:
  - Patient is 18 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID.

Certolizumab (Cimzia)

  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ixekizumab (Taltz) OR secukinumab (Cosentyx)

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 of the following alternatives
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), guselkumab (Tremfya), ixekizumab (Taltz), or risankizumab-rzaa (Skyrizi)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), guselkumab

Certolizumab (Cimzia)

(Tremfya), ixekizumab (Taltz), tofacitinib (Xeljanz), tofacitinib ER (Xeljanz XR), Risankizumab-Rzaa (Skyrizi), or Upadacitinib (Rinvoq)

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 6 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for Crohn's Disease such as corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine.
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2023

Chenodiol (Chenodal)

Specific Therapeutic Class: *Bile Acid*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months (one renewal only)

Diagnosis Considered for Coverage:

- Gallstones

Prescribing Restriction:

- Quantity Limit*: A quantity sufficient for a 30 day supply based on prescribed dose
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Gallstones**, approve if:
  - Patient is 18 years of age or older
  - Presence of radiolucent cholesterol stones in well-opacifying gallbladders confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance (for 6 months), intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ursodiol
  - Patient is not a candidate for surgery (e.g., due to systemic disease or age)
  - Prescribed dose does not exceed 18 mg/kg/day

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy
- Total treatment duration does not exceed 24 months
- If request is for a dose increase, new dose does not exceed 18 mg/kg/day

References: N/A

Last review/revision date: 4/2022

Chlorambucil (Leukeran)

Specific Therapeutic Class: *Antineoplastic Agent, Alkylating Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic lymphocytic leukemia
- Hodgkin lymphoma
- Non-Hodgkin lymphomas

Prescribing Restriction:

- Quantity Limit*: Authorized quantity sufficient for a 30 day supply
- Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Lymphocytic Leukemia**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis is confirmed by an FDA-approved test

- For the diagnosis of **Hodgkin Lymphoma**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis is confirmed by an FDA-approved test

- For the diagnosis of **Non-Hodgkin Lymphoma**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis is confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Chlorambucil (Leukeran)

References: N/A

Last review/revision date: 7/2022

Cholic Acid (Cholbam)

Specific Therapeutic Class: *Bile Acid*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Bile acid synthesis disorder due to single enzyme defect
- Peroxisomal disorders including Zellweger spectrum disorders in patients that exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

Prescribing Restriction:

- Quantity Limit*: Up to 10 to 15 mg/kg (once daily or in 2 divided doses) or up to 11 to 17 mg/kg (once daily or in 2 divided doses) in patients with concomitant familial hypertriglyceridemia
- Prescriber restriction: Prescriber must be a Hepatologist or Gastroenterologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Bile Acid Synthesis Disorder due to Single Enzyme Defect,** approve if:
  - Patient diagnosis was confirmed by an FDA-approved biochemical or genetic test

- For the diagnosis of **Peroxisomal Disorders**, approve if:
  - Patient diagnosis was confirmed by an FDA-approved biochemical or genetic test
  - The requested agent will be used as adjunctive treatment

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation that liver function has improved (ASLT/ALT, bilirubin, etc) from baseline

References: N/A

Last review/revision date: 10/2023

Cladribine (Mavenclad)

Specific Therapeutic Class: *Antineoplastic Agent, Antimetabolite; Immunosuppressant Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*: #20 tablets per year
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - Patient does not have a current malignancy, HIV, or active chronic infections (e.g., hepatitis or tuberculosis)

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - Patient does not have a current malignancy, HIV, or active chronic infections (e.g., hepatitis or tuberculosis)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 9/2023

Cobimetinib (Cotellic)

Specific Therapeutic Class: *Antineoplastic Agent, MEK Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Melanoma (unresectable or metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Melanoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has an ejection fraction grater the 50%
  - Patient's disease is unresectable OR metastatic
  - Patient has a documented BRAF V600E OR V600K mutation confirmed by an FDA-approved test
  - The requested agent will be used in combination with vemurafenib (Zelboraf)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Cobimetinib (Cotellic)

Last review/revision date: 4/2022

Codeine

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **acute or chronic pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
    - Indication of chronic cancer pain
    - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
    - There is documented failure despite compliance to long-acting opiates
    - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

Codeine

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Compounded Medications

Formulary Status: Non-Formulary/Prior Authorization required

Coverage Duration:

- Initial: Not to exceed 3 months
- Reauthorization: 6 months

Diagnosis Considered for Coverage:

- Diagnosis appropriate for medications contained in the compounded product.

Prescriber Restriction

- Quantity Limit* 30 day supply

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Current therapy
- Other medications that have been used for diagnosis
- Comorbidities

Coverage Criteria:

The plan may authorize coverage of compounded prescription medications with an ingredient cost greater than or equal to $200 when ALL of the following criteria are met:

- The indication, therapeutic amount, and route of administration of each of the active ingredients in the compound is FDA-approved, or CMS-recognized compendia supported
- All of the active ingredients included in the compound are FDA-approved medications (bulk chemicals are not FDA approved)
- If there are existing clinical coverage criteria for any of the active ingredients, those criteria must also be met for these ingredients
- Any one (1) of the following:
  - There is a current supply shortage of the commercial product
  - The Member has a medical need for a dosage form or dosage strength that is not commercially available
  - The Member had a trial and intolerance or contraindication to the commercially available product (e.g., allergen/preservative/dye-free, palatability for pediatrics, adverse effects to binders/fillers/other active ingredients)
  - The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

Note: All of the active ingredients included in the compound need to be included on the request for authorization

References: N/A

Last review/revision date: 12/2022

Continuous Glucose Monitors (Non-Formulary)

Standard/Specific Therapeutic Class: *Medical Supplies/Diabetic Supplies*

Formulary Status:

- Formulary:
  - Freestyle Libre
- Non-formulary:
  - All other blood glucose meters

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Diabetes

Prescribing Restriction:

- Quantity Limit*: 1 unit per year (365 days)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

**If patient meets PA criteria a tier override will be provided*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- Approve only if patient is using an insulin pump that is incompatible with Freestyle libre continuous blood glucose monitors confirmed by pump manufacturer

References: N/A

Last review/revision date: 7/2023

Crizotinib (Xalkori)

Specific Therapeutic Class: *Antineoplastic Agent, Anaplastic Lymphoma Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Anaplastic large cell lymphoma (relapsed or refractory)
- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Anaplastic Large Cell Lymphoma,** approve if:
  - Patient is at least 1 year of age
  - Tumor is positive for ALK mutation confirmed by an FDA-approved test
  - Disease is relapsed or refractory

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Disease is advanced, recurrent, or metastatic
  - ONE of the following (confirmed by an FDA-approved test)
    - Tumor is anaplastic lymphoma kinase (ALK)-positive
    - Tumor is ROS1-positive

- For the diagnosis of **Inflammatory Myofibroblastic Tumor,** approve if:
  - Patient is 1 year of age or older
  - Tumor is positive for ALK mutation confirmed by an FDA-approved test

Crizotinib (Xalkori)

- Disease is unresectable, recurrent, or refractory

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Cyclosporine (Verkazia)

Specific Therapeutic Class: *Calcineurin Inhibitor; Immunosuppressant Agent*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 3 months
- Continuation: 3 months

Diagnosis Considered for Coverage:

- Vernal keratoconjunctivitis

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Ophthalmologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Vernal Keratoconjunctivitis**, approve if:
  - Patient is 4 years of age or older
  - Patient diagnosis is confirmed by FDA-approved criteria
  - Patient does not have keratoconjunctivitis sicca
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 different combinations of topical mast cell stabilizers and topical antihistamines
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two oral antihistamines in combination with topical therapy
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following topical corticosteroids: prednisolone, dexamethasone, fluorometholone, or loteprednol etabonate (Note: at least one of the topical corticosteroid trials must include either prednisolone 1% or dexamethasone 0.1%)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has been compliant with therapy confirmed by fill history (if non-compliant, patient must meet initiation of therapy criteria)
- There is documentation of improvement in the patient's symptoms

References: N/A

Cyclosporine (Verkazia)

Last review/revision date: 4/2022

Cysteamine (Cystaran, Cystadrops, Cystagon, Procysbi)

Specific Therapeutic Class: *Anticystine Agent; Urinary Tract Product; Ophthalmic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial:
  - Cysteamine (Cystagon, Procysbi): 3 months
  - Cysteamine (Cystaran, Cystadrops): 6 months
- Continuation: Indefinite (all products)

Diagnosis Considered for Coverage:

- Corneal cystine crystal accumulation in patients with cystinosis (Cystaran, Cystadrops)
- Management of Nephropathic Cystinosis (Cystagon, Procysbi)

Prescribing Restriction:

- Quantity Limit*:
  - Cystaran: 4 bottles/28 days
  - Cystadrop: 2 bottles/25 days
  - Cystagon, Procysbi: 1.95g/m2/day with max of 30 day supply
- Prescriber restriction: See individual indications below

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Corneal Cystine Crystal Accumulation in patients with Cystinosis (Cystaran and Cystadrops only)**, approve if:
  - Requested agent is prescribed by or in consultation with an ophthalmologist
  - There is documentation of the presence of corneal cystine accumulation
  - For Cystaran the dose does not exceed 1 drop in each eye every hour while awake (1 bottle/week).
  - For Cystadrops, the dose does not exceed 1 drop in each eye 4 times per day while awake

- For the diagnosis of **Nephropathic Cystinosis (Cystagon and Procysbi only)**, approve if:
  - The diagnosis is confirmed by having all of the following:
    - Elevated baseline white blood cell (WBC) cystine levels > 2 nmol/1/2cystine/mg protein
    - CTNS gene mutation confirmed by an FDA-approved test
    - Clinical symptoms consistent with nephropathic cystinosis including electrolyte imbalances (e.g., Fanconi Syndrome) and polyuria
  - Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
  - Must use Cystagon as preferred therapy and must provide the following chart documentation of at least one of the following when requesting Procysbi:

Cysteamine (Cystaran, Cystadrops, Cystagon, Procysbi)

- Chart documentation of an adequate trial of immediate release cysteamine (Cystagon) with an inadequate response despite dose titration and compliance with therapy demonstrated by inadequately controlled WBC cystine levels
- The physician must provide relevant written documentation of laboratory and/or objective values [e.g., WBC cysteine levels, physician progress notes; or Subjective, Objective, Assessment, and Plan (SOAP note) information representing the physician's interaction with the member] as well as clinical rationale explaining why Cystagon has not produced the same clinical results as would be expected with the use of Procysbi (They are the same chemical entity)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For Cystagon & Procysbi:
  - Currently receiving medication or member has previously met initial approval criteria
  - Chart documentation that the member's condition has improved based upon the prescriber's assessment while on therapy and reduction in WBC cystine levels since starting treatment with cysteamine (Cystagon) or cysteamine delayed-release capsule (Procysbi)

References: N/A

Last review/revision date: 4/2022

Dabrafenib (Tafinlar)

Specific Therapeutic Class: *Antineoplastic Agent, BRAF Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Melanoma
- Non-small cell lung cancer (metastatic)
- Anaplastic thyroid cancer (locally advanced or metastatic)
- Solid tumors (unresectable or metastatic)
- Glioma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Melanoma**, approve if:
  - Patient is 18 years of age or older
  - Patient does not have wild type BRAF melanoma confirmed by an FDA-approved test
  - If cancer is resectable, all of the following:
    - There is lymph node involvement
    - Requested agent will be used after complete resection
    - Requested agent will be used in combination with trametinib (Mekinist)
    - Patient has a BRAF V600E or BRAF V600K mutation as detected by anDA-approved test
  - If Cancer is unresectable OR metastatic, one of the following:
    - Requested agent will be used as monotherapy and meet all of the following:
      a. Patient has a BRAF V600E mutation confirmed by an FDA-approved test
    - Requested agent will be used as combination therapy with trametinib (Mekinist) and all the following:

Dabrafenib (Tafinlar)

a. Patient has a BRAF V600E or BRAF V600K mutation confirmed by an FDA-approved test

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient does not have wild type BRAF NSCLC confirmed by an FDA-approve test
  - The requested agent will be used in combination with trametinib (Mekinist)
  - The patient has a BRAF V600E mutation as detected by an FDA-approved test

- For the diagnosis of **Anaplastic Thyroid Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient does not have wild type BRAF ATC confirmed by an FDA-approved test
  - The patient has locally advanced or metastatic disease
  - The requested agent will be used in combination with trametinib (Mekinist)
  - The patient has a BRAF V600E mutation as detected by an FDA-approved test
  - There are no satisfactory locoregional treatment options available

- For the diagnosis of **Solid Tumors**, approve if:
  - Patient is 6 years of age or older
  - Patient has unresectable or metastatic disease
  - Patient has a BRAF V600E mutation as detected by an FDA-approved test
  - The requested agent will be used in combination with trametinib (Mekinist)
  - Patient has progressed following previous treatment
  - No satisfactory alternative treatment options available
  - Patient does not have colorectal cancer

- For the diagnosis of **Glioma**, approve if:
  - Patient is 1 year of age or older
  - The patient requires systemic therapy
  - Patient has low grade glioma confirmed by an FDA-approved test
  - Patient has a BRAF V600E mutation as detected by an FDA-approved test
  - The requested agent will be used in combination with trametinib

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Dabrafenib (Tafinlar)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2023

Dacomitinib (Vizimpro)

Specific Therapeutic Class: *Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Disease is advanced OR metastatic
  - Patient is positive for at least one of the following epidermal growth factor receptor (EGFR) mutations as detected by and FDA-approved test:
    - Exon 19 deletion
    - Exon 21 L858R substitution

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Dacomitinib (Vizimpro)

References: N/A

Last review/revision date: 1/2023

Danicopan (Voydeya)

Specific Therapeutic Class: *Complement Factor D Inhibitor; Complement Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Paroxysmal nocturnal hemoglobinuria (PNH)

Prescribing Restriction:

- Quantity Limit: #180 tablets per 30 days
- Prescriber restriction: Hematologist

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Medication history

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Paroxysmal Nocturnal Hemoglobinuria (PNH),** approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of PNH confirmed by an FDA-approved test
  - Patient has clinically significant Extravascular Hemolysis (EVH) with documentation of the following:
    - Hgb ≤ 9.5 g/dL
    - ARC ≥120 x 10^9/L
  - Patient has been taking ravulizumab (Ultomiris) or eculizumab (Soliris) for ≥6 months

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Documentation of positive clinical response to therapy (e.g., increased or stabilized Hgb levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.)

References: N/A

Last review/revision date: 6/2024

Daprodustat (Jesduvroq)

Specific Therapeutic Class: *Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Anemia due to chronic kidney disease

Prescribing Restriction:

- Quantity Limit*: #30 tablets per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Nephrologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Anemia due to Chronic Kidney Disease (CKD)**, approve if:
  - Patient has a confirmed diagnosis of CKD
  - Patient has been receiving dialysis for at least four months
  - Patient hemoglobin < 11 g/dL
  - There is documentation of trial and failure for at least 6 weeks with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use epoetin alfa (Epogen, Procrit) or epoetin alfa-epbx (Retacrit)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Hemoglobin < 12 g/dL
- Medication is used for appropriate indication and at appropriate dose
- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Darbepoetin Alfa (Aranesp)

Specific Therapeutic Class: *Colony Stimulating Factor; Erythropoiesis-Stimulating Agent (ESA); Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Anemia due to chemotherapy in patients with cancer
- Anemia due to chronic kidney disease

Prescribing Restriction:

- Quantity Limit*:
- 10mcg, 25mcg, 40mcg, 60mcg, 100mcg, 150mcg, 200mcg, 300mcg: #4 vials or prefilled syringes per 28 days
- 500mcg: #1 vial or prefilled syringe per 21 days
- Prescriber restriction: Hematologist/Oncologist, Nephrologist, Hepatologist, or Infectious Disease physician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Anemia due to Chemotherapy in Patients with Cancer**, approve if:
  - Hemoglobin < 10 g/dL
  - Patient is undergoing palliative treatment, OR on myelosuppressive chemotherapy without other identifiable cause of anemia, OR is refusing blood transfusions
  - Patient does NOT meet one of the following:
    - Patient with cancer not receiving chemotherapy
    - Patients on non-myelosuppressive chemotherapy (e.g., NOT breast, non–small cell lung, head and neck, lymphoid, and cervical cancers)
    - Patients receiving myelosuppressive chemotherapy with curative intent

- For the diagnosis of **Anemia due to Chronic Kidney Disease**, approve if:
  - Hemoglobin is < 10 g/dL
  - Patient has a confirmed diagnosis of CKD

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Hemoglobin < 12 g/dL
- If taking for chemotherapy induced anemia, patient is still receiving chemotherapy

References: N/A

Darbepoetin Alfa (Aranesp)

Last review/revision date: 6/2022

Darolutamide (Nubeqa)

Specific Therapeutic Class: *Antineoplastic Agent, Antiandrogen*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prostate cancer (nonmetastatic, castration-resistant)
- Prostate cancer (metastatic, hormone-sensitive)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prostate Cancer**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - All of the following:
      a. Disease is non-metastatic
      b. Disease is castration resistant OR recurrent
      c. One of the following:
         i. Patient has had a bilateral orchiectomy
         ii. The requested agent will be used in combination with a gonadotropin-releasing hormone (GnRH) analog
    - All of the following:
      a. Disease is metastatic
      b. Disease is hormone-sensitive
      c. The requested agent will be used in combination with docetaxel within 6 weeks after the start of darolutamide (Nubeqa)
      d. One of the following:

Darolutamide (Nubeqa)

i. Patient has had a bilateral orchiectomy
ii. The requested agent will be used in combination with a gonadotropin-releasing hormone (GnRH) analog

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Dasatinib (Sprycel)

Specific Therapeutic Class: *Antineoplastic Agent, BCR-ABL Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute lymphoblastic leukemia
- Chronic myeloid leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Lymphoblastic Leukemia,** approve if:
  - Patient is 1 year of age or older
  - Patient is Philadelphia chromosome-positive (Ph+) confirmed by an FDA-approved test
  - If the patient is 18 years of age or older, there is documentation of trial and failure, resistance, or intolerance to at least 1 prior therapy

- For the diagnosis of **Chronic Myeloid Leukemia**, approve if:
  - Patient is 1 year of age or older
  - Patient is Philadelphia chromosome-positive (Ph+) confirmed by an FDA-approved test
  - If the patient is 18 years of age or older, one of the following:
    - Patient is newly diagnosed CML in the chronic phase
    - Patient is in chronic, accelerated, or myeloid or lymphoid blast phase and there is documentation of trial and failure, resistance, or intolerance to imatinib and at least 1 other prior therapy

- For the diagnosis of **Off-Label Indications**, approve if:

Dasatinib (Sprycel)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 5/2022

Decitabine-Cedazuridine (Inqovi)

Specific Therapeutic Class: *Antineoplastic Agent, Antimetabolite, DNA Methylation Inhibitor, Cytidine Deaminase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Myelodysplastic syndromes
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Myelodysplastic Syndromes,** approve if:
  - Patient is 18 years of age or older
  - Patient has at least 1 of the following French-American-British subtypes:
    - Refractory anemia
    - Refractory anemia with ringer sideroblasts
    - Refractory anemia with excess blasts
    - Chronic myelomonocytic leukemia (CMML)
  - Patient meets criteria for one of the following International Prognostic Scoring System groups:
    - Intermediate-1
    - Intermediate-2
    - High-risk

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Decitabine-Cedazuridine (Inqovi)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 5/2022

Deferasirox (Jadenu & Exjade)

Standard/Specific Therapeutic Class: Miscellaneous, Agents to Treat Metallic Poison
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Chronic iron overload due to blood transfusions or non-transfusion dependent thalassemia syndromes
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*: FDA approved dose based on weight
- Prescriber restriction: Initially prescribed or being followed by a hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Dose
- Labs (e.g., serum ferritin level)
- Concurrent therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Chronic Iron Overload due to Blood Transfusion**, approve if:
  - Patient is 2 years of age or older
  - Patient is transfusion dependent
  - Serum ferritin consistently greater than 1000 mcg/L
  - Not being used in combination with other chelator therapies
  - eGFR is 40ml/min/1.73m^2 or higher

- For diagnosis of **Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes**, approve if:
  - Patient is 10 years of age or older
  - Diagnosis of thalassemia syndrome confirmed by an FDA-approved test
  - Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight
  - Serum ferritin level on ≥ 2 measurements one month apart of > 300 mcg/L
  - Not being used in combination with other chelator therapies
  - eGFR is 40ml/min/1.73m^2 or higher

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Diagnosis of chronic iron overload due to blood transfusion
- Serum ferritin is NOT consistently below 500 mcg (if consistently < 500 mcg/L, therapy must be discontinued)

Deferasirox (Jadenu & Exjade)

References: N/A

Last review/revision date: 3/2023

Deferiprone (Ferriprox)

Standard/Specific Therapeutic Class: Miscellaneous, Agents to Treat Metallic Poison
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Chronic iron overload due to blood transfusions or non-transfusion dependent thalassemia syndromes, sickle cell disease, or other anemias
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*: FDA approved dose based on weight
- Prescriber restriction: Initially prescribed or being followed by a Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Dose
- Labs (e.g., serum ferritin level)
- Concurrent therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Chronic Iron Overload due to Blood Transfusion**, approve if:
  - Patient is 8 years of age or older
  - Patient is transfusion dependent
  - Serum ferritin consistently greater than 1000 mcg/L
  - Not being used in combination with other chelator therapies
  - eGFR is 40ml/min/1.73m^2 or higher

- For diagnosis of **Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes, Sickle Cell Disease, or other Anemias,** approve if:
  - Patient is 3 years of age or older
  - Diagnosis of thalassemia syndrome, sickle cell disease, or another anemia confirmed by an FDA-approved test
  - Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight
  - Serum ferritin level on ≥ 2 measurements one month apart of > 300 mcg/L
  - Not being used in combination with other chelator therapies
  - eGFR is 40ml/min/1.73m^2 or higher

Deferiprone (Ferriprox)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Diagnosis of chronic iron overload due to blood transfusion
- Serum ferritin is NOT consistently below 500 mcg (if consistently < 500 mcg/L, therapy must be discontinued)

References: N/A

Last review/revision date: 2/2022

Deflazacort (Emflaza)

Specific Therapeutic Class: *Corticosteroid, Systemic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Duchenne muscular dystrophy

Prescribing Restriction:

- Quantity Limit*: A sufficient quantity for a 30 day supply and a dose less than or equal to 0.9mg/kg/day
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Duchenne Muscular Dystrophy**, approve if:
  - Patient is 2 years of age or older
  - Documented mutation of dystrophin gene confirmed by an FDA-approved test
  - Patient has onset of weakness before 2 years of age, and serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) at some stage in their illness
  - Patient is ambulatory
  - Patient has had a baseline eye examination
  - Patient has had a baseline behavioral health evaluation
  - Patient had a baseline bone mineral density (BMD) screening completed (including date and results)
  - Patient is or will be taking adequate calcium and vitamin D supplementation
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use prednisone or prednisolone for at least 12 months
  - The request is for an FDA approved dose

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- The patient is ambulatory
- Physician attests that the patient's muscle strength has stabilized or improved since the starting treatment
- Patient's prior claim history shows consistent therapy (monthly fills)
- Physician attests patient has had repeat eye and BMD screening as appropriate
- The request is for an FDA approved dose

Deflazacort (Emflaza)

References: N/A

Last review/revision date: 9/2023

Denosumab (Prolia & Xgeva)

Specific Therapeutic Class: *Bone-Modifying Agent; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Bone metastases from solid tumors (Xgeva only)
- Giant cell tumor of bone (Xgeva only)
- Hypercalcemia of malignancy (Xgeva only)
- Multiple myeloma (Xgeva only)
- Osteoporosis/Bone loss (Prolia only)

Prescribing Restriction:

- Quantity Limit*:
  - Denosumab (Prolia): #1 ml per 6 months
  - Denosumab (Xgeva):
    - Initial: #5.1ml per 28 days
    - All subsequent fills: #1.7ml per 28 days
- Prescriber restriction:
  - Denosumab (Prolia): N/A
  - Denosumab (Xgeva): Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Bone Metastases from Solid Tumors (Xgeva only)**, approve if:
  - Patient has a diagnosis of solid tumor related bone metastases confirmed by an FDA-approved test
  - If the patient has hypocalcemia, it will be corrected prior to initiating therapy
  - There is documentation of trial and failure with documented compliance with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use bisphosphonates

- For the diagnosis of **Giant Cell Tumor of Bone (Xgeva only)**, approve if:
  - Patient has a diagnosis of giant cell tumor confirmed by an FDA-approved test
  - Patient is 12 years of age or older
  - If the patient has hypocalcemia, it will be corrected prior to initiating therapy

Denosumab (Prolia & Xgeva)

- There is documentation of trial and failure with documented compliance with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use bisphosphonates
- The patient's tumor is unresectable or surgical resection is likely to result in severe morbidity

- For the diagnosis of **Hypercalcemia of Malignancy (Xgeva only)**, approve if:
  - Patient has a confirmed diagnosis of malignancy confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use bisphosphonates

- For the diagnosis of **Multiple Myeloma (Xgeva only)**, approve if:
  - Patient has a diagnosis of multiple myeloma confirmed by an FDA-approved test
  - If the patient has hypocalcemia, it will be corrected prior to initiating therapy
  - There is documentation of trial and failure with documented compliance with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use bisphosphonates

- For the diagnosis of **Osteoporosis/Bone Loss (Prolia only),** approve if:
  - There is documentation of trial and failure with documented compliance with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use bisphosphonates
  - T-score < 2.5 OR T-score -1.0 and -2.5 with high risk of fracture or history of fracture
  - If the patient has hypocalcemia, it will be corrected prior to initiating therapy

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 2/2022

Deucravacitinib (Sotyktu)

Specific Therapeutic Class: *Janus Kinase Inhibitor; Tyrosine Kinase 2 Inhibitor*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Plaque psoriasis

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **at least 3 of the following alternatives**:
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to pre-existing disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of a negative TB test submitted with the request
  - There is documentation of baseline liver enzymes, triglycerides, and CPK
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), or risankizumab-rzaa (Skyrizi)

Deucravacitinib (Sotyktu)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has not experienced markedly elevated CPK and has not been diagnosed with myopathy or rhabdomyolysis
- Patient has not experienced liver transaminase elevations > 3x the ULN

References: N/A

Last review/revision date: 9/2023

Deutetrabenazine (Austedo)

Specific Therapeutic Class: *Central Monoamine-Depleting Agent; Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Chorea associated with Huntington disease
- Tardive dyskinesia

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Prescriber is a Neurologist or Psychiatrist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chorea Associated with Huntington Disease**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of Huntington's disease confirmed by an FDA-approved test
  - Physician attests that patient has had a baseline electrocardiogram (EKG) and is aware of the possible risk of QT prolongation
  - Documentation of baseline Total Maximal Chorea (TMC) score ≥ 8, or Total Functional Capacity (TFC) score ≥ 5 from UHDRS has been provided with the request
  - There is documentation of trial and failure with documented compliance or, intolerance of, contraindication to, or inability to use tetrabenazine

- For the diagnosis of **Tardive Dyskinesia**, approve if:
  - Patient is 18 years of age or older
  - Documented baseline evaluation with one of the following scoring tools: Abnormal Involuntary Movement Scale (AIMS) > 10 OR Extrapyramidal Symptom Rating Scale (ESRS) > 20

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For the diagnosis of chorea associated with Huntington's disease:
  - Documentation was provided that demonstrates clinical symptom improvement (i.e., reduction of total chorea score from UHDRS)

Deutetrabenazine (Austedo)

- For diagnosis of moderate to severe tardive dyskinesia:
  - Documentation was provided that demonstrates improvement in AIMS or ESRS scores

References: N/A

Last review/revision date: 9/2022

Dextromethorphan-Quinidine (Nuedexta)

Specific Therapeutic Class: *N-Methyl-D-Aspartate (NMDA) Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pseudobulbar Affect (PBA)

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pseudobulbar Affect (PBA)**, approve if:
  - Patient is 18 years of age or older
  - Patient has a history including at least one of the following:
    - Alzheimer's disease or other dementias
    - Stroke
    - Traumatic brain injury (TBI)
    - Multiple Sclerosis (MS)
    - Parkinson's disease
    - Lou Gehrig's disease (ALS)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use selective serotonin reuptake inhibitors and tricyclic antidepressants
  - A baseline ECG has been completed which demonstrated no significant abnormalities
  - The patient has no history of complete AV block, or has a pacemaker
  - The patient does not have a history of heart failure
  - The patient does not have a history of torsade's de pointes

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has experienced a positive clinical response from therapy

References: N/A

Dextromethorphan-Quinidine (Nuedexta)

Last review/revision date: 5/2022

Dichlorphenamide (Keveyis)

Specific Therapeutic Class: *Carbonic Anhydrase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Primary periodic paralysis

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Primary Periodic Paralysis**, approve if:
  - Patient is age 18 years or older
  - Patient has one of the following
    - Primary hyperkalemic periodic paralysis and related variants
    - Primary hypokalemic periodic paralysis and related variants
  - The diagnosis is confirmed by ONE of the following FDA-approved tests:
    - Genetic testing
    - Provocative testing
    - Electromyography
    - Muscle biopsy
  - There is documentation that lifestyle modifications, dietary restrictions and exercise restrictions have been maximally challenged
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to us acetazolamide
  - Patient has no signs of hepatic impairment
  - Patient does not have severe pulmonary disease
  - Patient is not and will not be taking high-dose aspirin with the requested agent

References: N/A

Last review/revision date: 9/2023

Diroximel Fumarate (Vumerity)

Specific Therapeutic Class: *Fumaric Acid Derivative*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*: #112/28 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 9/2023

Dornase alfa (Pulmozyme)

Specific Therapeutic Class: *Enzyme; Mucolytic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cystic Fibrosis

Prescribing Restriction:

- Quantity Limit*: #75 ml per 30 days
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Cystic Fibrosis**, approve if:
     - The patient has a diagnosis of cystic fibrosis confirmed by an FDA-approved test
     - The requested agent will not be used as monotherapy
     - The medication is being prescribed at a dose that is within FDA approved guidelines

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2022

Dupilumab (Dupixent)

Specific Therapeutic Class: *Systemic interleukin-4 receptor antagonist monoclonal antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Atopic dermatitis (mild, moderate, or severe eczema)
- Eosinophilic asthma for add on maintenance therapy of moderate to severe corticosteroid dependent asthma
- Eosinophilic Esophagitis
- Prurigo nodularis
- Rhinosinusitis (chronic) with nasal polyposis as add on therapy
- Other diagnoses: see off-label criteria

Prescribing Restriction:

- Quantity Limit*:
  - Atopic dermatitis: #2 syringes for initiation and #1 syringe every other week (300mg syringe)
    - Initial: #3 syringes per 28 days
    - Continuation: #2 syringes per 28 days
  - Asthma: #2 syringes for initiation and #1 syringe every other week (200 or 300mg syringes)
    - Initial: #3 syringes per 28 days
    - Continuation: #2 syringes per 28 days
  - Eosinophilic Esophagitis
    - Initial & continuation: #4 syringes per 28 days
  - Prurigo nodularis: #2 syringes for initiation and #1 syringe every other week (300mg syringe)
    - Initial: #3 syringes per 28 days
    - Continuation: #2 syringes per 28 days
  - Rhinosinusitis: #1 syringe every other week (300mg syringe)
    - Initial & continuation: #2 syringes per 28 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Atopic Dermatitis**, approve if:
  - Age > 6 months
  - Diagnosis of moderate to severe atopic dermatitis
  - Body surface area (BSA) involvement > 10%
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 high potency topical corticosteroid AND topical calcineurin

Dupilumab (Dupixent)

inhibitor (note: If patient meets approval criteria, a high-potency topical corticosteroid should be continued unless contraindicated)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use crisaborole (Eucrisa)
    - Prescribed by or in consultation with a Dermatologist, Pediatrician, Immunologist, or Allergist

- For the diagnosis of **Asthma**, approve if:
    - Diagnosis of moderate to severe asthma confirmed by an FDA-approved test
    - Patient age ≥ 12 years
    - Patient has experienced ≥ 2 exacerbations, within the last 12 months, requiring any of the following despite adherent use of controller therapy for at least 6 months (i.e., medium- to high-dose inhaled corticosteroid (ICS) plus either a long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindicated/intolerance):
        - Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
        - Urgent care visit or hospital admission
        - Intubation
    - One of the following:
        - Member has an absolute blood eosinophil count ≥150 cells/mcL within the past 3 months
        - Member is currently corticosteroid dependent
    - Prescribed by or in consultation with a pulmonologist, immunologist, or allergist
    - Will not be used concurrently with another monoclonal antibody for the treatment of asthma

- For the diagnosis of **Rhinosinusitis**, approve if:
    - Patient is 18 years of age or older
    - Diagnosis of chronic rhinosinusitis
    - Documented presence of nasal polyposis
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use intranasal or oral corticosteroids

- For the diagnosis of **Eosinophilic Esophagitis**, approve if:
    - Patient is 1 years of age or older
    - Patient weighs at least 15kg
    - Patient has eosinophil-predominant inflammation confirmed by esophageal biopsy
    - Patient has a peak value of ≥15 eosinophils per high power field (HPF) (or 60 eosinophils per mm^2) confirmed by esophageal biopsy
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to at least 3 months of lifestyle modification including elimination of food antigens that initiate the inflammatory process
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 1 oral PPI

Dupilumab (Dupixent)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least one formulary inhaled corticosteroid

- For the diagnosis of **Prurigo nodularis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of Prurigo nodularis confirmed by an FDA-approved test
  - Patient has at least 20 total lesions
  - Prescribed by or in consultation with a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 high potency topical corticosteroid AND topical calcineurin inhibitor (note: If patient meets approval criteria, a high-potency topical corticosteroid should be continued unless contraindicated)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing medication
- If for atopic dermatitis, documentation of improvement in BSA involvement from baseline

References: N/A

Last review/revision date: 5/2024

Duvelisib (Copiktra)

Specific Therapeutic Class: *Antineoplastic Agent, Phosphatidylinositol 3-Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic lymphocytic leukemia (CLL)
- Small lymphocytic lymphoma (SLL)
- Follicular lymphoma (relapsed or refractory)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL), OR Follicular Lymphoma,** approve if:
  - Patient is 18 years or age or older
  - Disease is relapsed or refractory
  - There is documented trial and failure or inability to use at least 2 prior therapies

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Duvelisib (Copiktra)

Last review/revision date: 5/2022

Echothiophate Iodide (Phospholine Iodide)

Specific Therapeutic Class: *Acetylcholinesterase Inhibitor; Ophthalmic Agent, Antiglaucoma; Ophthalmic Agent, Miotic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Open-Angle glaucoma
- Accommodative estropia

Prescribing Restriction:

- Quantity Limit*: 1 bottle/28 days
- Prescriber restriction: Prescribed by or in consultation with an Ophthalmologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Elevated Intraocular Pressure in Open-Angle Glaucoma**, approve if:
  - Patient does not have active uveal inflammation
  - Patient does not have angle-closure glaucoma without iridectomy
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 different classes of ocular treatments up to maximum doses, including:
    - prostaglandin analog (e.g., latanoprost, travoprost, bimatoprost)
    - a beta-adregeneric blocking agent (e.g, betaxolol, carteolol, levobunolol, timolol)
    - an alpha-2-adrenergic agonist (e.g., apraclonidine, brimonidine)
    - and/or a carbonic anhydrase inhibitor (e.g., brinzolamide or dorzolamide) as individual therapy or in combination products

- For the diagnosis of **Accommodative Estropia,** approve if:
  - Patient does not have active uveal inflammation
  - Patient has tried and failed or is unable to demonstrate compliance with bifocals or spectacles due to age, fit or lack of cooperation

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has been compliant with therapy confirmed by fill history (if non-compliant, patient must meet initiation of therapy criteria)

Echothiophate Iodide (Phospholine Iodide)

- There is documentation of improvement in the patient's symptoms

References: N/A

Last review/revision date: 3/2023

Edaravone (Radicava ORS)

Specific Therapeutic Class: *Free Radical Scavenger*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Amyotrophic Lateral Sclerosis (ALS)

Prescribing Restriction:

- Quantity Limit*: #70ml per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Amyotrophic Lateral Sclerosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has signs of lower motor neuron (LMN) degeneration confirmed by clinical, electrophysiological, or neuropathologic examination
  - Patient has signs of upper motor neuron (UMN) degeneration confirmed by clinical examination
  - Patient has progressive spread of signs within a region or to other regions and absence of both of the following:
    - Electrophysiological evidence of other disease processes that might explain the signs of LMN and/or UMN degenerations
    - Neuroimaging evidence of other disease processes that might explain the observed clinical and electrophysiological signs
  - Patient has a revised ALSFRS-R score with at least 2 points in each of the 12 items (total 48 points)
  - There is documentation of trial and failure or inadequate response with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use riluzole

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy
- Patient maintains a revised ALSFRS-R score with at least 2 points in each of the 12 items (total 48 points)

References: N/A

Last review/revision date: 5/2022

Eflapegrastim-xnst (Rolvedon)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*: 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome,** approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose
  - There is documentation of trial and failure (i.e., failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged anti-infectives) with an adequate trial (including dates, doses of therapy) of at least 2 pegfilgrastim biosimilar agents OR there is a documented medical reason (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using a biosimilar agent

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose
  - There is documentation of trial and failure (i.e., failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged anti-infectives) with an adequate trial (including dates, doses of therapy) of at least 2 pegfilgrastim biosimilar agents OR there is a documented medical reason (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using a biosimilar agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is still receiving chemotherapy

Eflapegrastim-xnst (Rolvedon)

References: N/A

Last review/revision date: 10/2022

Eflornithine (Iwilfin)

Specific Therapeutic Class: *Antineoplastic Agent, Ornithine Decarboxylase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- High-risk neuroblastoma (HRNB)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
- Prescriber restriction: Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **High-risk neuroblastoma (HRNB),** approve if:
  - Patient is 1 year of age or older
  - Patient has a diagnosis of neuroblastoma confirmed by an FDA-approved test
  - Patient has demonstrated a partial response or greater to prior multi-agent, multimodality therapy including anti-GD2 immunotherapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Eflornithine (Iwilfin)

References: N/A

Last review/revision date: 6/2024

Elacestrant (Orserdu)

Specific Therapeutic Class: *Antineoplastic Agent, Estrogen Receptor Antagonist, Selective Estrogen Receptor Degrader*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast Cancer (advanced or metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has advanced or metastatic disease
  - Patient is ER-positive confirmed by an FDA-approved test
  - Patient is HER2-negative confirmed by an FDA-approved test
  - Patient is ESR1-mutated confirmed by an FDA-approved test
  - Patient has experienced disease progression following at least one line of endocrine therapy
  - One of the following:
    - Patient is a postmenopausal female
    - Patient is a male

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Elacestrant (Orserdu)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 4/2023

Elagolix-Estradiol-Norethindrone & Elagolix (Oriahnn)

Specific Therapeutic Class: *Estrogen, Progestin, and Gonadotropin Releasing Hormone Receptor combination*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women

Prescribing Restriction:

- Quantity Limit*: #56 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Heavy Menstrual Bleeding associated with Uterine Leiomyomas (Fibroids)**, approve if:
  - Patient is 18 years of age or older
  - Patient is premenopausal
  - If the fibroids are submucosal only, there is documentation submitted for failure or inability to undergo hysteroscopic resection of submucosal fibroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following:
    - Estrogen-progestin contraceptives
    - Progestin-only contraceptives
    - Progestin-releasing intrauterine device (IUD)
    - Oral Tranexamic acid
  - Patient is not at high risk of arterial, venous thrombotic, or thromboembolic disorders defined by ONE of the following:
    - Patient is >35 years of age and both of the following
      a. Is a current smoker
      b. Headaches with focal neurological symptoms or have migraine headaches with aura
    - Patient has a current or history of deep vein thrombosis or pulmonary embolism
    - Patient has known vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
    - Patient has thrombogenic valvular or thrombogenic rhythm diseases of the heart (ex. subacute bacterial endocarditis with valvular disease, or atrial fibrillation)

Elagolix-Estradiol-Norethindrone & Elagolix (Oriahnn)

        - Patient has inherited or acquired hypercoagulopathies
        - Patient has uncontrolled hypertension
    - Patient is not pregnant or planning to become pregnant
    - Patient does not have osteoporosis or hepatic disease
    - No current or history of breast cancer or other hormonally sensitive malignancies or increased risk for hormonally sensitive malignancies
    - No hepatic impairment or disease
    - Does not have undiagnosed abnormal uterine bleeding
    - Patient is not currently taking an organic anion transporting polypeptide (OATP)1B1 Inhibitor including: Atazanavir (Reyataz), Clarithromycin (Biaxin), Cobicistat (part of Stribild), Cyclosporine (Neoral, Gengraf, Sandimmune), Daclatasvir (Daklinza), Eltrombopag (Promacta), Erythromycin (E-mycin), Gemfibrozil (Lopid), Glecaprevir (Mavyret), Lopinavir/Ritonavir (Kaletra), Letermovir (Prevymis), Paritaprevir (Viekira Pak, Technivie), Pibrentasvir (Mavyret), Ritonavir/Lopinavir (Kaletra), Sacubitril (Entresto), Saquinavir (Invirase), Simeprevir (Olysio), Telithromycin (Ketek), Teriflunomide (Aubagio), Tipranavir (Aptivus), Rifampin, Velpatasvir (Epclusa, Vosevi), Voxilaprevir (Vosevi)
    - The prescribed dose is 2 capsules per day

II. **Continuation of Therapy for EXISTING Members** (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose
- Total treatment duration is less than 24 months

References: N/A

Last review/revision date: 1/2023

Elagolix (Orilissa)

Specific Therapeutic Class: *Gonadotropin Releasing Hormone Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Endometriosis

Prescribing Restriction:

- Quantity Limit*:
  - 150mg tablet: #30 tablets per 30 days
  - 200mg tablet: #60 tablets per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Obstetrics/Gynecologist or reproductive Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Endometriosis**, approve if:
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use two generic analgesics (ibuprofen, meloxicam, naproxen, etc.)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use combined oral contraceptive or progestin
  - Patient is premenopausal
  - The patient is 18 years of age or older
  - The patient is not pregnant
  - The patient does not have osteoporosis or significant hepatic impairment (Child-Pugh class B or C)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For elagolix (Orilissa) 150mg QD dose only, maximum 24 months total duration
- For elagolix (Orilissa) 200mg BID dose only, maximum 6 months total duration

References: N/A

Last review/revision date: 9/2023

Elbasvir-Grazoprevir (Zepatier)

Specific Therapeutic Class: *Antihepaciviral, NS3/4A Protease Inhibitor (Anti-HCV); NS5A Inhibitor; NS3/4A Inhibitor; NS5A Inhibitor*

Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 16 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 18 years of age or older
  - Patient has viral genotype 1or 4 confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glecaprevir/pibrentasvir (Mavyret)
  - The patient does not have decompensated cirrhosis

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Requested regimen and duration is appropriate per AASLD/IDSA guidelines

References: N/A

Last review/revision date: 8/2022

Elexacaftor-Tezacaftor-Ivacaftor (Trikafta)

Specific Therapeutic Class: *Cystic Fibrosis Transmembrane Conductance Regulator Corrector; Cystic Fibrosis Transmembrane Conductance Regulator Potentiator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cystic fibrosis

Prescribing Restriction:

- Quantity Limit*:
  - Tablets: #84 per 28 days
  - Granules: #56 per 28 days
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cystic Fibrosis**, approve if:
  - The patient is 2 years of age or older
  - The patient has a diagnosis of cystic fibrosis confirmed by an FDA-approved test
  - One of the following:
    - The patient is homozygous for the F508del mutation in the CFTR gene
    - The patient has a tezacaftor/ivacaftor-responsive mutation in the CFTR gene
  - The medication is being prescribed at a dose that is within FDA approved guidelines
  - If the request is for oral granules, the patient is greater than or equal to 2 years of age and less than 6 years of age

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2023

Eliglustat (Cerdelga)

Specific Therapeutic Class: *Enzyme Inhibitor; Glucosylceramide Synthase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Gaucher disease

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Gaucher Disease**, approve if:
  - Patient had a diagnosis is Gaucher disease, type 1 confirmed by an FDA-approved test
  - The patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (e.g., due to allergy, hypersensitivity, or poor venous access, etc.) to use enzyme replacement therapy
  - There is documentation of an FDA-approved test indicating that the patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PMs)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented improvement in ONE of the following:
  - Spleen volume
  - Hemoglobin level
  - Liver volume
  - Platelet count
  - Growth
  - Bone pain

References: N/A

Last review/revision date: 2/2022

Eltrombopag (Promacta)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent; Thrombopoietic Agent; Thrombopoietin Receptor Agonist*

Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Aplastic anemia
- Chronic hepatitis C infection-associated thrombocytopenia
- Immune thrombocytopenia

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Aplastic Anemia**, approve if:
  - Patient is 2 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use to immunosuppressive therapy
  - Platelet level < 50,000 mm^3

- For the diagnosis of **Chronic Hepatitis C Infection-Associated Thrombocytopenia**, approve if:
  - Patient is 18 years of age or older
  - Platelet level < 50,000 mm^3
  - Requested agent will be used in combination with interferon-based therapy for hepatitis C

- For the diagnosis of **Immune Thrombocytopenia,** approve if:
  - Patient is 1 year of age or older
  - Platelet level < 50,000 mm^3
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ONE of the following: glucocorticoids, intravenous immune globulin (IVIG), rituximab (Rituxan) if appropriate) or splenectomy

Eltrombopag (Promacta)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication
References: N/A
Last review/revision date: 10/2021

Eluxadoline (Viberzi)

Specific Therapeutic Class: *Gastrointestinal Agent, Miscellaneous*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Irritable Bowel Syndrome with Diarrhea (IBS- D)

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Gastroenterologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Irritable Bowel Syndrome with Diarrhea (IBS- D)**, approve if:
  - Patient is 18 years of age or older
  - Patient's diagnosis is confirmed by FDA-approved criteria
  - Patient has not had their gallbladder removed
  - Patient does not have known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction
  - Patient does not have a history of pancreatitis; structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
  - Patient does not have severe hepatic impairment (Child-Pugh class C)
  - There is documented failure of an anti-diarrheal agent (e.g., loperamide, diphenoxylate w/atropine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
  - There is documented failure of an antispasmodic (e.g., dicyclomine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy
- Patient has not experienced any of the following: gallbladder removal, pancreatitis, pancreatic duct obstruction, biliary duct obstruction, severe constipation, or a mechanical gastrointestinal obstruction

References: N/A

Last review/revision date: 4/2022

Emicizumab-Kxwh (Hemlibra)

Specific Therapeutic Class: *Antihemophilic Agent; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hemophilia A

Prescribing Restriction:

- Quantity Limit*: A quantity sufficient for a 28 day supply for doses within FDA-approved maximum doses
- Prescriber restriction: See criteria below

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hemophilia A,** approve if:
  - If the patient has a diagnosis of hemophilia A with Factor VIII inhibitors (hemophilia A with inhibitors), they meet all of the following:
    - The requested agent is prescribed for prophylactic use
    - One of the following:
      a. The patient's inhibitor level is ≥ 5 BU
      b. The patient has tried and had an inadequate response to Immune Tolerance Therapy (ITT) [Immune Tolerance Induction (ITI)]
      c. The patient is using a bypassing agent (Feiba, NovoSeven) for on- demand treatment and is not adequately controlled
      d. The patient is using a bypassing agent for prophylaxis and had an inadequate response
      e. The patient is using more than 5 doses per week of a bypassing agent
      f. The patient has a documented intolerance, FDA labeled contraindication or hypersensitivity to a bypassing agent
    - If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, and the prescriber has counseled the patient on the maximum dosages of Feiba to be used (i.e., no more than 100 u/kg/24 hours)
  - If the patient has a diagnosis of hemophilia A without Factor VIII inhibitors (hemophilia A), they meet both of the following:
    - The requested agent is being prescribed for prophylactic use
    - The prescriber has submitted documentation supporting ONE of the following:

Emicizumab-Kxwh (Hemlibra)

a. The patient has tried and failed to be adequately controlled on prophylaxis with a Factor VIII clotting factor agent (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) after at least 50 exposure days. Documentation including chart notes and/or treatment logs must be submitted
b. The patient has poor venous access. Documentation including chart notes must be submitted
c. The patient failed to achieve an adequate trough level while on clinically optimal dose and frequency of a Factor VIII clotting factor agent. Documentation including chart notes must be submitted
d. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to prophylaxis with a Factor VIII clotting factor agent

- The prescriber has discussed with the patient that a treatment log, documenting at least 6 months of bleeds prior to starting the requested agent, and which includes ALL of the following must be maintained and a copy will be submitted (via prescriber or pharmacy) for renewal purposes *note if a historical bleed log is unavailable, a new log must be started and submitted for renewal
  - Date of the bleed
  - The treatment used (include the brand name and number of units administered)
  - The number of doses required to treat the bleed
- The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or has consulted with a specialist in the area of the patient's diagnosis
- If the patient is using a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) or a bypassing agent (e.g., Feiba, NovoSeven) for prophylaxis treatment, the prophylaxis with the Factor VIII product or bypassing agent will be discontinued (on-demand treatment is acceptable to continue)
- The requested dose is within the FDA labeled dosing based on the patient's weight

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- The prescriber has provided a copy of the patient's treatment logs for bleeds that includes ALL of the following:
  - Date of bleed
  - The treatment used (include the brand name and number of units administered)
  - The number of doses required to treat the bleed
- ONE of the following:
  - The patient has shown clinical benefit since starting the requested agent (i.e., less breakthrough bleeds as documented in the treatment log)
  - The prescriber has submitted documentation supporting the continued use of the requested agent
- The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent

References: N/A

Last review/revision date: 9/2023

Enasidenib (Idhifa)

Specific Therapeutic Class: *Antineoplastic Agent, IDH2 Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia (relapsed/refractory)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia**, approve if:
  - Patient is 18 years of age or older
  - Disease is relapsed or refractory
  - Patient has a Isocitrate dehydrogenase-2 (IDH2) mutation confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 5/2022

Encorafenib (Braftovi)

Specific Therapeutic Class: *Antineoplastic Agent, BRAF Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Melanoma (unresectable or metastatic)
- Colorectal cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Melanoma,** approve if:
  - Patient is 18 years of age or older
  - Disease is unresectable or metastatic
  - Patient has a documented BRAF V600E or BRAF V600K mutation confirmed by and FDA-approved test
  - Patient does not have wild-type BRAF confirmed by an FDA-approved test
  - The requested agent will be used in combination with binimetinib (Mektovi)

- For the diagnosis of **Colorectal Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient has a documented BRAF V600E mutation confirmed by an FDA-approved test
  - Patient does not have wild-type BRAF confirmed by an FDA-approved test
  - The requested agent will be used in combination with cetuximab (Ebitux)
  - The requested agent will not be used as first line therapy

Encorafenib (Braftovi)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 5/2022

Entrectinib (Rozlytrek)

Specific Therapeutic Class: *Antineoplastic Agent, Tropomyosin Receptor Kinase (TRK) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Solid tumors
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient is ROS1-positive confirmed by an FDA-approved test

- For the diagnosis of **Solid Tumors,** approve if:
  - Patient is 12 years of age or older
  - Patient is metastatic OR surgical intervention is likely to cause severe morbidity
  - Patient has Neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation confirmed by an FDA-approved test
  - Patient has progressed following previous treatment OR they have no satisfactory alternative therapy

- For the diagnosis of **Off-Label Indications**, approve if:

Entrectinib (Rozlytrek)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Enzalutamide (Xtandi)

Specific Therapeutic Class: *Antineoplastic Agent, Antiandrogen*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prostate cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prostate Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has one of the following:
    - Castration-Resistant Prostate Cancer (CRPC)
    - Metastatic Castration-Sensitive Prostate Cancer (mCSPC)
    - Nonmetastatic castration-sensitive prostate cancer with biochemical recurrence (BCR) at high risk for metastasis (high-risk BCR)
  - One of the following:
    - Patient is receiving a gonadotropin-releasing hormone (GnRH) analog
    - Patient has had a bilateral orchiectomy
  - Patient will not receive dual therapy with another androgen receptor inhibitor

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)

Enzalutamide (Xtandi)

- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2024

Epinepherine (Auvi-Q)

Specific Therapeutic Class: *Alpha-/Beta- Agonist, antidote*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Emergency treatment of allergic reactions (Type I) including anaphylaxis

Prescribing Restriction:

- Quantity Limit*: #2 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Emergency Treatment of Allergic Reactions (Type I) including Anaphylaxis**, approve if:
  - Patient is 1 year of age or older
  - Patient weighs at least 7.5kg
  - The patient meets one of the following criteria:
    - Individual or caregiver has significant visual deficits requiring the need for an autoinjector with audio cues for self-administration
    - Documented inability to use generic epinephrine
  - Prescribed dose meets FDA recommended criteria:
    - If ≥ 30kg: 0.3mg
    - If 15-30kg: 0.15mg
    - If 7.5-15kg: 0.1mg

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 9/2023

Eplontersen (Wainua)

Specific Therapeutic Class: *Antisense Oligonucleotide*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN)

Prescribing Restriction:

- Quantity Limit*: 45mg per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Polyneuropathy of hereditary transthyretin-mediated amyloidosis**, approve if:
  - Patient is ≥ 18 years of age
  - Patient has a diagnosis of hereditary transthyretin-mediated amyloidosis confirmed by an FDA-approved test showing a mutation in the *TTR* gene
  - Patient is experiencing signs and symptoms of mild to moderate polyneuropathy
  - Patient does not have documented clinical symptoms of New York Heart Association Class III or IV heart failure
  - The requested agent will not be used concomitantly with another TTR silencer [Vutrisiran (Amvuttra), Inotersen (Tegsedi), or Patisiran (Onpattro)] or a TTR stabilizer [diflunisal or Tafamidis (Vyndaqel, Vyndamax)]
  - Patient does not have a history of, or a planned liver transplant

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has not received a liver transplant
- Patient is responding positively to therapy confirmed by improvement in symptoms, stabilization, or slowed progression of disease manifestations

References: N/A

Last review/revision date: 2/2024

Epoetin Alfa & Epoetin Alfa-epbx (Epogen, Procrit, Retacrit)

Specific Therapeutic Class: *Colony Stimulating Factor; Erythropoiesis-Stimulating Agent (ESA); Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Anemia due to chemotherapy in patients with cancer
- Anemia due to chronic kidney disease
- Anemia due to zidovudine in HIV-infected patients

Prescribing Restriction:

- Quantity Limit*:
  - 2,000U/mL, 3,000U/mL, 4,000U/mL and 10,000U/mL vials: #12 vials per month
  - 20,000U/mL, 20,000U/mL vials and 40,000U/mL vials: #4 vials per month
- Prescriber restriction: Hematologist/Oncologist, Nephrologist, Hepatologist, or Infectious Disease physician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Anemia due to Chemotherapy in Patients with Cancer**, approve if:
  - Hemoglobin < 10 g/dL
  - Patient is undergoing palliative treatment, OR on myelosuppressive chemotherapy without other identifiable cause of anemia, OR refusing blood transfusions
  - Patient does NOT meet any of the following:
    - Patient with cancer not receiving chemotherapy
    - Patients on non-myelosuppressive chemotherapy (e.g., NOT breast, non–small cell lung, head and neck, lymphoid, and cervical cancers)
    - Patients receiving myelosuppressive chemotherapy with curative intent

- For the diagnosis of **Anemia due to Chronic Kidney Disease**, approve if:
  - Hemoglobin < 10 g/dL
  - Patient has a confirmed diagnosis of CKD

- For the diagnosis of **Anemia due to Zidovudine in HIV-Infected Patients**, approve if:
  - Hemoglobin < 10 g/dL
  - Patient has a diagnosis of HIV confirmed by and FDA-approved test

Epoetin Alfa & Epoetin Alfa-epbx (Epogen, Procrit, Retacrit)

- Patient has an active prescription for zidovudine at a dose less than or equal to 4.2 grams per week

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Hemoglobin < 12 g/dL
- If taking for chemotherapy induced anemia, patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2021

Erdafitinib (Balversa)

Specific Therapeutic Class: *Antineoplastic Agent, Fibroblast Growth Factor Receptor (FGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Urothelial carcinoma (locally advanced or metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Urothelial Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - Disease is metastatic or locally advanced
  - Patient has susceptible FGFR3 or FGFR2 genetic alterations confirmed by an FDA-approved test
  - Patient experienced disease progression during or following at least one line of prior platinum containing chemotherapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Erdafitinib (Balversa)

References: N/A

Last review/revision date: 9/2023

Erlotinib (Tarceva)

Specific Therapeutic Class: *Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Pancreatic cancer (locally advanced, unresectable, or metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Disease is metastatic
  - Patient has an EGFR mutation (exon 19 deletions OR exon 21 L858R substitution mutations) confirmed by and FDA-approved test
  - The requested agent will not be used in combination with platinum-based chemotherapy

- For the diagnosis of **Pancreatic Cancer**, approve if:
  - Patient is 18 years of age or older
  - Disease is locally advanced, unresectable, or metastatic
  - The requested agent will be used as first line therapy
  - The requested agent will be used with gemcitabine (Infugem)

- For the diagnosis of **Off-Label Indications**, approve if:

Erlotinib (Tarceva)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Estramustine (Emcyt)

Specific Therapeutic Class: *Antineoplastic Agent, Alkylating Agent, Antimicrotubular*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Etanercept (Enbrel)

Therapeutic Category: *Antirheumatic, Disease Modifying; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis

Prescribing Restrictions:

- Quantity Limit*:
  - Rheumatoid arthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis
    - 25 mg #8 (syringes) or 4.08 ml (8 vials) per 28 days (25 mg 2x/week dosing) OR
    - 50 mg 3.92 ml per 28 days (1 kit, 4 syringes/pen injectors) (50 mg once weekly dosing)
  - Psoriasis:
    - Up to 50 mg 7.84 ml per 28 days (2 kits, 8 syringes/pen injectors) for the first 3 months (50 mg 2x/week dosing)
    - Then 50 mg 3.92 ml per 28 days (1 kit, 4 syringes/pen injectors) (50 mg once weekly dosing)
- Prescriber restriction: rheumatologist, dermatologist, or gastroenterologist (see specific diagnosis in Coverage Criteria)

**NOTE: for Juvenile Idiopathic Arthritis, dose should be 0.8 mg/kg once weekly (max 50 mg/dose) or 0.4 mg/kg 2x/week (max 25 mg/dose)*

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)

Etanercept (Enbrel)

  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist.
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)

Etanercept (Enbrel)

- UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a rheumatologist or dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 2/2024

Etoposide (Toposar)

Specific Therapeutic Class: *Antineoplastic Agent, Podophyllotoxin Derivative, Topoisomerase II Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Small cell lung cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - The requested agent will be used as first line therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Etrasimod (Velsipity)

Specific Therapeutic Class: *Sphingosine 1-Phosphate (S1P) Receptor Modulator*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Ulcerative colitis

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Gastroenterologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Drug is being prescribed by a Gastroenterologist
  - Patient has not experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months
  - Patient does not have Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2024

Everolimus (Afinitor, Afinitor Disperz)

Specific Therapeutic Class: *Antineoplastic Agent, mTOR Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer, advanced (Afinitor only)
- Neuroendocrine tumors (Afinitor only)
- Renal cell carcinoma, advanced (Afinitor only)
- Tuberous sclerosis complex-associated partial-onset seizures (Afinitor Disperz only)
- Tuberous sclerosis complex-associated renal angiomyolipoma (Afinitor only)
- Tuberous sclerosis complex-associated subependymal giant cell astrocytoma (Afinitor or Afinitor Disperz only)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer (Afinitor only)**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease
  - Patient is hormone receptor-positive (HR+) confirmed by an FDA-approved test
  - Patient is human epidermal growth factor receptor 2 (HER2)-negative confirmed by an FDA-approved test
  - The patient is postmenopausal
  - The patient has previously been treated with letrozole or anastrozole
  - The patient will also be receiving exemestane in combination with the requested agent

- For the diagnosis of **Neuroendocrine Tumors (Afinitor only)**, approve if:
  - Patient is 18 years of age or older

Everolimus (Afinitor, Afinitor Disperz)

- One of the following:
  - Patient has a locally advanced, metastatic, or unresectable progressive pancreatic neuroendocrine tumors
  - Patient has a progressive, well-differentiated, nonfunctional GI or lung neuroendocrine tumor that is unresectable, locally advanced, or metastatic

- For the diagnosis of **Renal Cell Carcinoma (Afinitor only)**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease
  - Patient has been previously treated with sunitinib or sorafenib

- For the diagnosis of **Tuberous Sclerosis Complex-Associated Partial-Onset Seizures (Afinitor Disperz only)**, approve if:
  - Patient is 2 years of age or older
  - Requested agent will be used as adjunctive therapy

- For the diagnosis of **Tuberous Sclerosis Complex-Associated Renal Angiomyolipoma (Afinitor only)**, approve if:
  - Patient is 18 years of age or older
  - Patient does not require immediate surgery

- For the diagnosis of **Tuberous Sclerosis Complex-Associated Subependymal Giant Cell Astrocytoma (Afinitor or Afinitor Disperz only),** approve if:
  - Patient is 1 year of age or older
  - Patient is not a candidate for curative surgical resection

- For the diagnosis of **Off-Label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 5/2022

Evolocumab (Repatha)

Specific Therapeutic Class: *Antilipemic Agent, PCSK9 Inhibitor; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Primary hyperlipidemia
  - Heterozygous Familial Hypercholesterolemia (HeFH)
  - Homozygous Familial Hypercholesterolemia (HoFH)
- Reduction of risk for myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease

Prescribing Restriction:

- Quantity Limit*:
  - Primary hyperlipidemia (including Heterozygous Familial Hypercholesterolemia (HeFH)) and Reduction of risk for myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease:
    - 140mg/ml: #2 per 28 days
    - 420mg/3.5ml: #1 per 28 days
  - Homozygous Familial Hypercholesterolemia (HoFH):
    - 420mg/3.5ml: #2 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose
- Lipid levels

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Primary Hyperlipidemia**, approve if:
  - Patient is 18 years of age or older*
  - Two fasting lipid panel labs within the past 12 months demonstrate abnormal LDL levels > 100mg/dL
  - Documented claim history or chart notes showing consistent therapy and trial with one high-intensity statin regimen (atorvastatin 40-80mg or rosuvastatin 20-40mg) with inadequate response still requiring additional LDL lowering, or a documented medical reason (e.g., intolerance, hypersensitivity) for not utilizing high-dose statin

Evolocumab (Repatha)

- If request indicates that the patient is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. Patient should have documentation of trial and failure with documented compliance of at least two statin therapies
- If ezetimibe is indicated below, it should be tried prior to PCSK9 inhibitor per table below OR there must be documentation of trial and failure with documented compliance, intolerance, contraindication, or inability to use ezetimibe
- If the patient has Heterozygous Familial Hypercholesterolemia (HeFH) or Homozygous Familial Hypercholesterolemia (HoFH), all of the following are met:
  - Pre-treatment LDL is greater than 190mg/dL AND one of the following:
    a. One of the following:
       i. Family history of myocardial infarction in first-degree relative < 60 years of age
       ii. Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
       iii. Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
       iv. Family history of tendinous xanthoma and/or arcus cornealis in first- or second degree relative
       v. Premature coronary artery disease (<21 years of age)
    b. One of the following:
       i. Family history of myocardial infarction in first-degree relative < 60 years of age
       ii. Functional mutation in LDL, apoB, or PCSK9 gene
       iii. Tendinous xanthoma
       iv. Arcus cornealis before age 45

- For the diagnosis of **Myocardial Infarction, Stroke, and Unstable Angina Requiring Hospitalization in Adults with Established Cardiovascular Disease**, approve if:
  - Two fasting lipid panel labs within the past 12 months demonstrate abnormal LDL levels > 70mg/dL
  - Documented claim history or chart notes showing consistent therapy and trial with one high-intensity statin regimen (atorvastatin 40-80mg or rosuvastatin 20-40mg) with inadequate response still requiring additional LDL lowering, or a documented medical reason (e.g., intolerance, hypersensitivity) for not utilizing high-dose statin
  - If request indicates that the patient is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. Patient should have documentation of trial and failure with documented compliance of at least two statin therapies
  - If ezetimibe is indicated below, it should be tried prior to PCSK9 inhibitor per table below OR there must be documentation of trial and failure with documented compliance, intolerance, contraindication, or inability to use ezetimibe

Evolocumab (Repatha)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient continues to receive stain and/or ezetimibe at maximally tolerated doses (unless there is appropriately documented trial and failure)
- There is documentation in LDL reduction while on therapy

**Patients aged 12 to 17 will be reviewed on a case-by-case basis*

Member Age	Co-Morbidities	LDL Level	Treatment Regimen
≥ 21 years old	• Stable Clinical ASCVD • **NO** other co-morbidities	>70-189mg/dL	1. Add EZETIMIBE to current statin therapy first 2. Add PCSK9 inhibitor **OR** replace with PCSK9 inhibitor second
≥ 21 years old	• Clinical ASCVD • **WITH** co-morbidities that increase likelihood of cardiovascular event [Diabetes Mellitus (DM), daily smoker, metabolic syndrome, etc.]	>70-189mg/dL	1. Add EZETIMIBE to current statin therapy first 2. Add PCSK9 inhibitor **OR** replace with PCSK9 inhibitor second
40-75 years old	• Diabetes (DM) and without ASCVD • No diabetes with ≥ 7.5% estimated 10-year risk for ASCVD	70-189mg/dL	1. Add EZETIMIBE to current statin therapy* 2. Add PCSK9 inhibitor **OR** replace with PCSK9 inhibitor second **May also consider bile acid sequestrant*

References: N/A

Last review/revision date: 9/2022

Fecal Microbiota (Vowst)

Specific Therapeutic Class: *Microbiota*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 days
- Continuation: N/A

Diagnosis Considered for Coverage:

- *Clostridioides difficile* infection (CDI) prophylaxis

Prescribing Restriction:

- Quantity Limit*: #12 per 365 days
- Prescriber restriction: Prescribed by or in consultation with an Infectious Disease Specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of ***Clostridioides difficile* infection prophylaxis,** approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of ≥2 recurrent CDI episodes (≥3 total CDI episodes)
  - Patients current episode of CDI is controlled defined by <3 unformed/loose stools/day for 2 consecutive days
  - Patient has received 10-21 days of antibiotic therapy for the current episode of CDI
  - There is documentation of a positive stool test for *Clostridioides difficile* within 30 days prior to the request
  - The requested agent is prescribed concurrently with magnesium citrate or polyethylene glycol which will be used the day prior to the first dose of the requested agent

References: N/A

Last review/revision date: 6/2023

Fedratinib (Inrebic)

Specific Therapeutic Class: *Antineoplastic Agent, FLT3 Inhibitor, Janus Associated Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Myelofibrosis
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Myelofibrosis**, approve if:
  - Patient is 18 years or age or older
  - Patient has intermediate-2 or high-risk primary or secondary disease

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 5/2022

Fenfluramine (Fintepla)

Specific Therapeutic Class: *Anticonvulsant, Miscellaneous; Serotonin 5HT-2 Receptor Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Seizures associated with Dravet Syndrome

Prescribing Restriction:

- Quantity Limit*: #360ml per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Seizures Associated with Dravet Syndrome**, approve if:
  - The patient is 2 years of age or older
  - The patient has NOT used monoamine oxidase inhibitors within the past 14 days and will not be taking them at any time while taking the requested agent
  - The patient is not and will not be taking azelastine, linezolid, orphenadrine, or thalidomide while receiving Fintepla
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 other anticonvulsants
  - The prescribed dose is no more than 0.35mg/kg twice daily and the total daily dose is less than or equal to 26mg/day

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Fentanyl Transdermal (Duragesic)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #15 patches per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - One of the following:
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **morphine sulfate ER tablets (MS Contin) at an adequate (equianalgesic) dose**
    - There is documentation of pain caused by active cancer

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Ferric Citrate (Auryxia)

Specific Therapeutic Class: *Iron Preparations; Phosphate Binder*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hyperphosphatemia
- Iron deficiency anemia

Prescribing Restriction:

- Quantity Limit*: #360 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hyperphosphatemia**, approve if:
  - Patient has a diagnosis of chronic kidney disease and is receiving dialysis
  - Patient is 18 years of age or older
  - One of the following:
    - Phosphate level > 5.5 mg/dl on sevelamer carbonate (Renvela)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sevelamer carbonate (Renvela)

- For the diagnosis of **Iron Deficiency Anemia**, approve if:
  - Patient is 18 years of age or older
  - Patient is diagnosed with iron deficiency of anemia with chronic kidney disease
  - Patient is not receiving dialysis
  - Patient has a documented intolerance to, contraindication, or treatment failure with at least TWO alternative oral iron therapies (e.g., ferrous sulfate, ferrous fumarate, ferrous gluconate)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 11/2022

Filgrastim (Neupogen)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Acute myeloid leukemia following induction or consolidation chemotherapy
- Bone marrow transplantation
- Chemotherapy-induced myelosuppression in nonmyeloid malignancies
- Acute hematopoietic radiation injury syndrome
- Peripheral blood progenitor cell collection and therapy
- Severe chronic neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 300/0.5 ml syringe: up to 7 ml per 28 days (should be billed in increments of 0.5 ml)
  - 300/ml vial: up to 14 ml per 28 days (should be billed in increments of 1 ml)
  - 480/0.8 ml syringe: up to 11.2 ml per 28 days (should be billed in increments of 0.8 ml)
  - 480/1.6 ml vial: up to 22.4 ml per 28 days (should be billed in increments of 1.6 ml)
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnoses listed in **"Diagnosis Considered for Coverage"** listed above, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose
  - There is documentation of trial and failure (i.e., failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged anti-infectives) with an adequate trial (including dates, doses of therapy) of at least 2 biosimilar agents OR there is a documented medical reason (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using a biosimilar agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Filgrastim (Neupogen)

Last review/revision date: 6/2022

Filgrastim-aafi (Nivestym)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Acute myeloid leukemia following induction or consolidation chemotherapy
- Bone marrow transplantation
- Chemotherapy-induced myelosuppression in nonmyeloid malignancies
- Peripheral blood progenitor cell collection and therapy
- Severe chronic neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 300/0.5 ml syringe: up to 7 ml per 28 days (should be billed in increments of 0.5 ml)
  - 480/0.8 ml syringe: up to 11.2 ml per 28 days (should be billed in increments of 0.8 ml)
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnoses listed in **"Diagnosis Considered for Coverage"** above, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 6/2022

Filgrastim-ayow (Releuko)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Acute myeloid leukemia following induction or consolidation chemotherapy
- Bone marrow transplantation
- Chemotherapy-induced myelosuppression in nonmyeloid malignancies
- Peripheral blood progenitor cell collection and therapy
- Severe chronic neutropenia

Prescribing Restriction:

- Quantity Limit*: #10 syringes per 28 days
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnoses listed in **"Diagnosis Considered for Coverage"** above, approve if:
     - Patient is currently being treated by a Hematologist or Oncologist
     - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication

References: N/A

Last review/revision date: 6/2022

Filgrastim-sndz (Zarxio)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Acute myeloid leukemia following induction or consolidation chemotherapy
- Bone marrow transplantation
- Chemotherapy-induced myelosuppression in nonmyeloid malignancies
- Peripheral blood progenitor cell collection and therapy
- Severe chronic neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 300/0.5 ml syringe: up to 7 ml per 28 days (should be billed in increments of 0.5 ml)
  - 480/0.8 ml syringe: up to 11.2 ml per 28 days (should be billed in increments of 0.8 ml)
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnoses listed in **"Diagnosis Considered for Coverage"** above, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 6/2022

Fingolimod (Gilenya, Tascenso ODT)

Specific Therapeutic Class: *Sphingosine 1-Phosphate (S1P) Receptor Modulator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 10 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - Patient has not had a recent myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure.
  - Patient does not have a history of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome unless patient has a pacemaker
  - Patient has a baseline QTc interval < 500 msec
  - Patient does not have any cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
  - If the prescription is written for Fingolimod ODT (Tascenso ODT), the patient weighs less than or equal to 40kg

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 10 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - Patient has not had a recent myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure.
  - Patient does not have a history of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome unless patient has a pacemaker

Fingolimod (Gilenya, Tascenso ODT)

- Patient has a baseline QTc interval < 500 msec
- Patient does not have any cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
- If the prescription is written for Fingolimod ODT (Tascenso ODT), the patient weighs less than or equal to 40kg

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 9/2023

Fostamatinib (Tavalisse)

Specific Therapeutic Class: *Spleen Tyrosine Kinase (Syk) Inhibitor; Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Immune thrombocytopenia

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Immune Thrombocytopenia,** approve if:
  - Patient is 18 years of age or older
  - Platelet level < 50,000 mm^3
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ONE of the following: glucocorticoids, intravenous immune globulin (IVIG), rituximab (Rituxan) if appropriate) or splenectomy
  - Platelet level < 50,000 mm3

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2021

Fruquintinib (Fruzaqla)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Colorectal cancer, metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Colorectal cancer,** approve if:
  - Patient has a diagnosis of colorectal cancer confirmed by an FDA-approved test
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient has disease progression following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan- based chemotherapy
  - Patient has disease progression following treatment with anti-VEGF therapy
  - If the patient has *RAS* wild-type disease, they have disease progression following treatment with anti-EGFR therapy
  - The requested agent will be used as monotherapy

- For the diagnosis of **Off-Label Indications**, approve if:

Fruquintinib (Fruzaqla)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2024

Furosemide (Furoscix)

Specific Therapeutic Class: *Antihypertensive; Diuretic, Loop*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Congestive heart failure

Prescribing Restriction:

- Quantity Limit*: #6 per 90 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Congestive Heart Failure**, approve if:
  - Patient has a diagnosis of heart failure confirmed by guideline-based laboratory parameters and echocardiogram
  - Patient is classified as NYHA class II or III
  - Patient does not have a history of flash pulmonary edema
  - Patient does not have ascites or hepatic cirrhosis
  - Patient has an estimated creatine clearance >30ml/min using the Cockcroft-Gault equation
  - Patient is and has been taking background diuretic therapy confirmed by refill history
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following:
    - Oral torsemide
    - Oral bumetanide
    - An oral loop diuretic PLUS a thiazide diuretic for sequential nephron blockade

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 11/2022

Futibatinib (Lytgobi)

Specific Therapeutic Class: *Antineoplastic Agent, Fibroblast Growth Factor Receptor (FGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cholangiocarcinoma, intrahepatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cholangiocarcinoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has intrahepatic disease
  - Patient has unresectable locally advanced or metastatic disease
  - Patient has received previous treatment for the disease
  - Patient has one of the following:
    - Fibroblast Growth Factor Receptor 2 (FGFR2) gene fusions confirmed by an FDA-approved test
    - Other gene rearrangements confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Futibatinib (Lytgobi)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 11/2022

Ganaxolone (Ztalmy)

Specific Therapeutic Class: *Antiseizure Agent, Miscellaneous; Gamma-Aminobutyric Acid (GABA) A Receptor Positive Modulator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Prescribing Restriction:

- Quantity Limit*: 1080ml per 30 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
- For the diagnosis of **Seizures associated with Cyclin-Dependent Kinase-Like 5 (CDKL5) Deficiency Disorder,** approve if:
  - Patient is 2 years of age or older
  - Patient has a diagnosis of CDKL5 deficiency confirmed by an FDA-approved genetic test
  - There is documentation of trial and failure with documented compliance for at least 3 months, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 other antiepileptic therapies
  - Documentation of baseline monthly seizure frequency is submitted with the request

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- There is documentation of a sustained decrease in monthly seizure frequency from baseline

References: N/A

Last review/revision date: 10/2023

Gefitinib (Iressa)

Specific Therapeutic Class: *Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Disease is metastatic
  - Patient has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations confirmed by and FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Gefitinib (Iressa)

Last review/revision date: 1/2023

Gilteritinib (Xospata)

Specific Therapeutic Class: *Antineoplastic Agent, FLT3 Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia (relapsed or refractory)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia,** approve if:
  - Patient is 18 years of age or older
  - Disease is relapsed or refractory
  - Patient has a FLT3 mutation confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Glasdegib (Daurismo)

Specific Therapeutic Class: *Antineoplastic Agent, Hedgehog Pathway Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia**, approve if:
  - Patient is 18 years or age or older
  - One of the following:
    - Patient is 75 years of age or older
    - Patient has comorbidities that preclude the use of intensive induction chemotherapy
  - The requested agent will be used in combination with low-dose cytarabine

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Glasdegib (Daurismo)

Last review/revision date: 9/2023

Glatiramer Acetate (Copaxone, Glatopa)

Specific Therapeutic Class: *Biological, Miscellaneous*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*:
  - 20 mg: #30 mL/30 days
  - 40 mg: #12 ml/28 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - Will not be used in combination with any other disease-modifying MS agent

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - Will not be used in combination with any other disease-modifying MS agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 9/2023

Glecaprevir-Pibrentasvir (Mavyret)

Specific Therapeutic Class: *Antihepaciviral, NS3/4A Protease Inhibitor (Anti-HCV); NS5A Inhibitor; NS3/4A Inhibitor; NS5A Inhibitor*

Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 16 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)

Prescribing Restriction:

- Quantity Limit*: #84 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 3 years of age or older
  - Patient has viral genotype 1,2,3,4,5, or 6 confirmed by an FDA-approved test
  - Patient does not have decompensated cirrhosis
  - Patient does not have moderate or severe hepatic impairment (Child-Pugh Class B or C)
  - The requested agent will not be administered with atazanavir or rifampin

References: N/A

Last review/revision date: 8/2022

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists & Glucose-Dependent Insulinotropic Polypeptides (GIP)

Specific Therapeutic Class: *Glucose-Dependent Insulinotropic Polypeptide (GIP)/Glucagon-Like Peptide (GLP-1) Receptor Agonists*

Formulary Status: Formulary, Non-Formulary, PA required

Coverage Duration:

- Type II Diabetes Mellitus
  - Indefinite
- Obesity/Weight loss
  - Initial: 6 months
  - Continuation: 12 months

Diagnosis Considered for Coverage:

- Type II Diabetes Mellitus
- Obesity/Weight loss

Prescribing Restriction:

- Quantity Limit*:
  - Dulaglutide (Trulicity): #2ml per 28 days
  - Exenatide (Byetta):
    - 5mcg Pen: #1.2ml per 28 days
    - 10mcg pen: #2.4ml per 28 days
  - Exenatide ER (Bydureon):
    - Bydureon Pen: #4 per 28 days
    - Bydureon BCise: #3.4ml per 28 days
  - Liraglutide (Saxenda): #15ml per 30 days
  - Liraglutide (Victoza): #9ml per 28 days
  - Lixisenatide (Adlyxin): #6ml per 28 days
  - Semaglutide (Ozempic): #3ml per 28 days
  - Semaglutide (Rybelsus): #30 per 30 days
  - Semaglutide (Wegovy):
    - 0.5ml pens: #2ml per 28 days
    - 0.75ml pens: #3ml per 28 days
  - Tirzepatide (Mounjaro): #2ml per 28 days
  - Tirzepatide (Zepbound): #2ml per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists & Glucose-Dependent Insulinotropic Polypeptides (GIP)

- For the diagnosis of **Type II Diabetes Mellitus**, approve if:
  - If the patient is currently, or has taken a GLP-1 inhibitor within the last 120 days:
    - The patient has a documented glycated hemoglobin (A1C) of greater than or equal to 7%
  - If the patient is a newly starting a GLP-1 inhibitor and has not filled on within the last 120 days:
    - The patient has a documented glycated hemoglobin (A1C) of greater than or equal to 7%
    - There is documentation of trial and failure with documented compliance for at least 90 days to use at least 1 oral antihyperglycemic or insulin
    - If the request is for liraglutide (Saxenda), semaglutide (Wegovy), or tirzepatide (Zepbound), deny
    - If the request is for dulaglutide (Trulicity) or exenatide ER (Bydureon), patient is 10 years of age or older
    - If the request is for exenatide (Byetta) or tirzepatide (Mounjaro), patient is 18 years of age or older
    - If the request is for liraglutide (Victoza):
      a. Patient is 10 years of age or older
      b. There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dulaglutide (Trulicity), exenatide ER (Bydureon), exenatide (Byetta), or tirzepatide (Mounjaro) for 60 days
    - If the request is for lixisenatide (Adlyxin), semaglutide (Ozempic), or semaglutide (Rybelsus):
      a. Patient is 18 years of age or older
      b. There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dulaglutide (Trulicity), exenatide ER (Bydureon), exenatide (Byetta), or tirzepatide (Mounjaro) for 60 days

- For the diagnosis of **Obesity/weight loss**, approve if:
  - If the request is for liraglutide (Saxenda) or semaglutide (Wegovy)
    - The patient is 12 years of age or older
    - If the patient is 18 years of age or older, the patient meets one of the following:
      a. The patient has a body mass index (BMI) ≥30 kg/m2
      b. The patient has a BMI ≥27 kg/m2 and at least ONE of the following:
        i. Hypertension
        ii. Dyslipidemia
        iii. Diabetes
        iv. Other weight-related comorbid condition (will be reviewed on a case-by-case basis)
    - If the patient is 12 – 17 years of age the patient meets both of the following:
      a. Weight greater than or equal to 60kg
      b. BMI corresponding to 30 kg/m2 or greater for adults by international cut-offs using the Cole criteria
    - The patient does not have a history of pancreatitis

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists & Glucose-Dependent Insulinotropic Polypeptides (GIP)

- There is documented trial and failure (less than 5% loss in total body weight) with documented compliance to at least 6 months of lifestyle modifications including diet (~500kcal daily deficit) and exercise (at least 150 minutes per week)

- If the request is for tirzepatide (Zepbound):
  - The patient is 18 years of age or older and meets one of the following:
    a. The patient has a body mass index (BMI) ≥30 kg/m2
    b. The patient has a BMI ≥27 kg/m2 and at least ONE of the following:
       i. Hypertension
       ii. Dyslipidemia
       iii. Diabetes
       iv. Other weight-related comorbid condition (will be reviewed on a case-by-case basis)
  - The patient does not have a history of pancreatitis
  - There is documented trial and failure (less than 5% loss in total body weight) with documented compliance to at least 6 months of lifestyle modifications including diet (~500kcal daily deficit) and exercise (at least 150 minutes per week)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- For the diagnosis of Type II Diabetes Mellitus:
  - Patient is stable and continuing the medication
- For the diagnosis of Obesity/weight loss:
  - Patient is stable and continuing the medication
  - Medication is used for appropriate indication and at an appropriate dose
  - Patient has experienced and maintained at least a 4% decrease in bodyweight from baseline
  - Patient has not experienced any episodes of pancreatitis

References: N/A

Last review/revision date: 3/2024

Glutamine (Endari)

Specific Therapeutic Class: *Amino Acid; Gastrointestinal Agent, Miscellaneous*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Sickle cell disease

Prescribing Restriction:

- Quantity Limit*:
  - Weight < 30 kg: 60 packets per 30 days
  - Weight 30 to 65 kg: 120 packets per 30 days
  - Weight > 65 kg: 180 packets per 30 days
- Prescriber restriction: Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Sickle Cell Disease**, approve if:
  - Patient has a diagnosis of Sickle cell disease confirmed by an FDA-approved test
  - Documentation provided that patient had 2 or more crises in the last 12 months
  - Documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use hydroxyurea at the maximum tolerated dose with compliance per submitted documentation or refill history within the last 6 months (or medical reason was provided why patient is unable to use hydroxyurea)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Prescriber attests member had reduction in the number of sickle cell crises

References: N/A

Last review/revision date: 7/2022

Glycerol Phenylbutyrate (Ravicti)

Specific Therapeutic Class: *Urea Cycle Disorder (UCD) Treatment Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Urea cycle disorders

Prescribing Restriction:

- Quantity Limit*: #525 ml per 30 days
- Prescriber restriction: Prescribed by or in consultation with a specialist in metabolic diseases or a geneticist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Urea Cycle Disorders**, approve if:
  - The patient has a diagnosis of ONE of the following urea cycle disorders confirmed by FDA-approved enzymatic or genetic testing:
    - carbamoylphosphate synthetase I deficiency [CPSID]
    - ornithine transcarbamylase deficiency [OTCD]
    - argininosuccinic acid synthetase deficiency [ASSD]
    - argininosuccinic acid lyase deficiency [ASLD]
    - arginase deficiency [ARGD]
  - The patient has a diagnosis of hyperammonemia AND ALL of the following:
    - The patient has elevated ammonia levels according to the patient's age [Neonate: plasma ammonia level 150 µmol/L (>260 µg/dL) or higher; Older child or adult: plasma ammonia level >100 µmol/L (>175 µg/dL)]
    - The patient has a normal anion gap
    - The patient has a normal blood glucose level
  - The patient does not have acute hyperammonemia
  - The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and, if clinically appropriate, essential amino acid supplementation
  - The patient will be using the requested agent as adjunctive therapy to dietary protein restriction

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

Glycerol Phenylbutyrate (Ravicti)

- There is documented improvement in ammonia levels from baseline

References: N/A

Last review/revision date: 3/2022

Golimumab (Simponi)

Therapeutic Category: *Antipsoriatic Agent; Antirheumatic, Disease Modifying; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriatic arthritis
- Ulcerative colitis
- Polyarticular Juvenile Idiopathic Arthritis

Prescribing Restrictions:

- Quantity Limit:
  - Ankylosing spondylitis, psoriatic arthritis, polyarticular juvenile idiopathic arthritis, rheumatoid arthritis
    - 50 mg per 28 days
  - Ulcerative colitis
    - Initial: 200 mg at week 0, 200 mg at week 2
    - Maintenance: 100 mg every 28 days
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - ONE of the following:

Golimumab (Simponi)

        - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
            - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
        - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e, drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
    - Patient is 18 years of age or older
    - Patient has diagnosis of ankylosing spondylitis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed by or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following alternatives: etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), ixekizumab (Taltz), or secukinumab (Cosentyx)

- For diagnosis of **Psoriatic Arthritis**, approve if:
    - Patient is 2 years of age or older
    - Diagnosis of psoriatic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug is being prescribed by a Rheumatologist or Dermatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), tofacitinib (Xeljanz), tofacitinib ER (Xeljanz XR), Risankizumab-Rzaa (Skyrizi), or upadacitinib (Rinvoq)

Golimumab (Simponi)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 to 17 years of age
  - Patient has diagnosis of juvenile idiopathic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 10/2023

Granisetron (Sancuso)

Specific Therapeutic Class: *Antiemetic; Selective 5-HT3 Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prevention of chemotherapy related nausea and vomiting

Prescribing Restriction:

- Quantity Limit*: #1 per chemotherapy cycle
- Prescriber restriction: Prescribed by or in consultation with an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prevention of Chemotherapy Related Nausea and Vomiting**, approve if:
  - Patient is receiving moderately to highly emetogenic chemotherapy in a cycle that is at least 2 consecutive days
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use an oral 5-HT3 Receptor Antagonist

References: N/A

Last review/revision date: 7/2022

Guselkumab (Tremfya)

Therapeutic Category: *Antipsoriatic Agent; Interleukin-23 Inhibitor; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Plaque psoriasis
- Psoriatic arthritis

Prescribing Restrictions:

- Quantity Limit:
  - Initial: 100 mg (#1) weeks 0 and 4
  - Maintenance: 100 mg (#1) every 8 weeks
- Prescriber restriction: Dermatologist or Rheumatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis

Guselkumab (Tremfya)

- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a Rheumatologist or Dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 2/2024

Hydrocodone ER (Zohydro)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following alternatives
    - short-acting opiates
    - morphine sulfate ER tablets (MS Contin)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Hydrocodone-Acetaminophen (Vicodin, Xodol)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*

Formulary Status:

- Formulary
  - Hydrocodone/acetaminophen (Vicodin) 2.5-325, 5-325, 7.5-325, 10-325 mg tablet
- Non-Formulary
  - Hydrocodone/acetaminophen (Xodol) 5-300, 7.5-300, 10-300 mg tablet; oral solution

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year
- Non-formulary drug: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:

Hydrocodone-Acetaminophen (Vicodin, Xodol)

- Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
- Indication of chronic cancer pain
- There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
- There is documented failure despite compliance to long-acting opiates
- Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Hydromorphone (Dilaudid)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status:

- Formulary
  - Hydromorphone (Dilaudid) tablet

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
    - Indication of chronic cancer pain
    - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)

Hydromorphone (Dilaudid)

- There is documented failure despite compliance to long-acting opiates
- Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Hydromorphone ER (Exalgo)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ALL of the following alternatives at an adequate (equianalgesic) dose
    - Oxymorphone immediate release
    - Morphine sulfate ER tablets (MS Contin) or capsules (Kadian)
    - Fentanyl patches (Duragesic) AND Oxycodone ER (Oxycontin)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Hydroxyprogesterone Caproate (Makena)

Specific Therapeutic Class: *Progestin*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: up to 37 weeks of gestation
- Continuation: N/A

Diagnosis Considered for Coverage:

- Preterm birth prevention

Prescribing Restriction:

- Quantity Limit*: Not to exceed #5 ml per 35 days (5 ml vial) or #4 ml (4 x 1 ml vial) per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Preterm Birth Prevention,** approve if:
  - Patient is 16 years of age or older
  - History of previous spontaneous preterm birth before 37 weeks gestation
  - Treatment to be started between 16 weeks 0 days gestation and 20 weeks 6 days gestation
  - Documented expected delivery date or current gestational age provided with request
  - Patient does not have a history of thrombosis or thromboembolic disorders, known, suspected, or history of breast cancer or other hormone-sensitive cancer, cholestatic jaundice of pregnancy, liver tumors, benign or malignant, or active liver disease, or uncontrolled hypertension

References: N/A

Last review/revision date: 1/2023

Hydroxyurea (Siklos)

Specific Therapeutic Class: *Antineoplastic Agent, Miscellaneous*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Sickle cell anemia

Prescribing Restriction:

- Quantity Limit*: Sufficient quantity for a 30 day supply based on prescribed dose
- Prescriber restriction: Prescribed by or in consultation with a Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Sickle Cell Anemia**, approve if:
  - Patient is 2 years of age or older
  - Prescriber agrees to monitor blood counts throughout treatment with the requested agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic hydroxyurea capsules

References: N/A

Last review/revision date: 9/2023

Ibrutinib (Imbruvica)

Specific Therapeutic Class: *Antineoplastic Agent, Bruton Tyrosine Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic graft-versus-host disease (refractory)
- Chronic lymphocytic leukemia
- Small lymphocytic lymphoma
- Mantle cell lymphoma (previously treated)
- Marginal zone lymphoma (relapsed/refractory)
- Waldenström macroglobulinemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Graft-Versus-Host Disease,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure to at least 1 systemic therapy

- For the diagnosis of **Chronic Lymphocytic Leukemia,** approve if:
  - Patient is 18 years of age or older
  - Patient has a 17p deletion confirmed by an FDA-approved test

- For the diagnosis of **Small Lymphocytic Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has a 17p deletion confirmed by an FDA-approved test

Ibrutinib (Imbruvica)

- For the diagnosis of **Mantle Cell Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure to at least 1 prior therapy

- For the diagnosis of **Marginal Zone Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure to at least 1 prior anti-CD20-based therapy

- For the diagnosis of **Waldenström Macroglobulinemia,** approve if:
  - Patient is 18 years of age or older

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2022

Icatibant (Firazyr, Sajazir)

Specific Therapeutic Class: *Selective Bradykinin B2 Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Hereditary angioedema

Prescribing Restriction:

- Quantity Limit*: #12 syringes per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Hereditary Angioedema**, approve if:
     - Patient is 18 years of age or older
     - Patient has a diagnosis of hereditary angioedema confirmed by an FDA-approved test
     - The requested agent will be used for treatment of HAE attacks
     - The requested agent will not be used in combination with other agents for the treatment of HAE attacks

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - Patient has a documented response to therapy

References: N/A

Last review/revision date: 3/2022

Idelalisib (Zydelig)

Specific Therapeutic Class: *Antineoplastic Agent, Phosphatidylinositol 3-Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic lymphocytic leukemia
- Follicular B-cell non-Hodgkin lymphoma
- Small lymphocytic lymphoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Lymphocytic Leukemia**, approve if:
  - Patient is 18 years of age or older
  - Disease is relapsed with documentation of at least 1 prior therapy
  - The requested agent will be used in combination with rituximab

- For the diagnosis of **Follicular B-cell Non-Hodgkin Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Disease is relapsed with documentation of at least 2 prior systemic therapies

- For the diagnosis of **Small Lymphocytic Lymphoma**, approve if:
  - Patient is 18 years of age or older
  - Disease is relapsed with documentation of at least 2 prior systemic therapies

- For the diagnosis of **Off-Label Indications**, approve if:

Idelalisib (Zydelig)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Iloprost (Ventavis)

Specific Therapeutic Class: *Prostacyclin; Prostaglandin; Vasodilator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary arterial hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #270 mL per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Pulmonary arterial hypertension (PAH),** approve if:
     - Patient has a diagnosis of PAH confirmed by RHC
     - There is documentation that the patient has WHO functional class (FC) II or III symptoms

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Last review/revision date: 6/2024

Infigratinib (Truseltiq)

Specific Therapeutic Class: *Antineoplastic Agent, Fibroblast Growth Factor Receptor (FGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cholangiocarcinoma, unresectable locally advanced or metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cholangiocarcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has previously treated, unresectable locally advanced, or metastatic disease
  - Patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Infigratinib (Truseltiq)

Last review/revision date: 7/2022

Infliximab-dyyb (Zymfentra)

Therapeutic Category: *Immunosuppressant Agent; Monoclonal Antibody; Tumor Necrosis Factor (TNF) Blocking Agent*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Ulcerative Colitis

Prescribing Restrictions:

- Quantity Limit: #2 per 28 days
- Prescriber restriction: Gastroenterologist

Clinical Information Required for Review:

- Medical records
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 6/2024

Inotersen (Tegsedi)

Specific Therapeutic Class: *Antisense Oligonucleotide*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR)

Prescribing Restriction:

- Quantity Limit*: #4 per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis**, approve if:
  - Patient is 18 years of age or older
  - Documented presence of a transthyretin (TTR) mutation confirmed by an FDA-approved test
  - Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy
  - Patient has not had a liver transplant
  - If previously treated with tafamidis, patient has discontinued treatment for 2 weeks prior to initiation of the requested agent
  - If previously treated with diflunisal, patient has discontinued treatment for 3 days prior to initiating the requested agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy – including but not limited to improvement in any of the following parameters:
  - Neuropathy (motor function, sensation, reflexes, walking ability)
  - Nutrition (body mass index)
  - Cardiac parameters (Holter monitoring, echocardiography, electrocardiogram, plasma BNP or NT-proBNP, serum troponin)
  - Renal parameters (creatinine clearance, urine albumin)
  - Ophthalmic parameters (eye exam)
- Patient has not had a liver transplant

Inotersen (Tegsedi)

References: N/A

Last review/revision date: 9/2023

Interferon Alfa-2b (Intron A)

Specific Therapeutic Class: *Antineoplastic Agent, Biological Response Modulator; Interferon*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- AIDS-related Kaposi Sarcoma
- Chronic Hepatitis B
- Condylomata Acuminata
- Follicular lymphoma
- Hairy cell leukemia
- Malignant melanoma

Prescribing Restriction:

- Quantity Limit*: a quantity sufficient for a 30 day supply
- Prescriber restriction: See individual criteria below

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy
- Prescriber specialty

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **AIDS-related Kaposi Sarcoma**, approve if:
  - Patient is 18 years of age or older
  - Patient is HIV positive confirmed by and FDA-approved test
  - Prescribed by or in consultation with an Infectious Disease Specialist

- For the diagnosis of **Chronic Hepatitis B**, approve if:
  - Patient is 1 year of age or greater
  - Patient has compensated liver disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use peg-interferon products

- For the diagnosis of **Condylomata Acuminata**, approve if:
  - Patient is 18 years of age or older
  - Prescribed by a Gynecologist or Dermatologist
  - Prescribed dose is less than or equal to the maximum FDA recommended dose

Interferon Alfa-2b (Intron A)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 1 of the following: podophyllotoxin or imiquimod

- For the diagnosis of **Follicular Lymphoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has follicular non-Hodgkin lymphoma confirmed by an FDA-approved test
  - The requested agent will be used in conjunction with anthracycline-containing combination chemotherapy
  - Prescribed by an Oncologist or Hematologist

- For the diagnosis of **Hairy Cell Leukemia,** approve if:
  - Patient is 18 years of age or older
  - Prescribed by an Oncologist or Hematologist

- For the diagnosis of **Malignant Melanoma**, approve if:
  - Patient is 18 years of age or older
  - Requested agent will be used as an adjuvant to surgical treatment
  - Patient is free of disease but at high risk for systemic recurrence within 56 days of surgery
  - Prescribed by an Oncologist or Hematologist

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Requested quantity does not exceed FDA approved or standard off-label dose

References: N/A

Last review/revision date: 7/2022

Interferon Alfa-N3 (Alferon N)

Specific Therapeutic Class: *Interferon*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 8 weeks
- Continuation: 8 weeks

Diagnosis Considered for Coverage:

- Condylomata acuminata

Prescribing Restriction:

- Quantity Limit*: 0.05ml per wart twice weekly x 8 weeks
- Prescriber restriction: Gynecologist or Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Condylomata Acuminata**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 1 of the following: podophyllotoxin or imiquimod
  - Prescribed dose is less than or equal to the maximum FDA recommended dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient meets initiation of therapy criteria above
- It has been at least 3 months since first treatment course

References: N/A

Last review/revision date: 7/2022

Interferon Beta-1a (Avonex, Rebif)

Specific Therapeutic Class: *Interferon*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*:
  - Interferon beta-1a (Avonex): #4 per 28 days
  - Interferon beta-1a (Rebif): #6 mL (12 syringes) per 28 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent

II. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 9/2023

Interferon Beta-1b (Betaseron, Extavia)

Specific Therapeutic Class: Interferon
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*:
- Interferon beta-1b (Betaseron): #14 per 28 days
- Interferon beta-1b (Extavia): #15 per 30 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
  - Will not be used in combination with any other disease-modifying MS agent

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
  - Will not be used in combination with any other disease-modifying MS agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

Interferon Beta-1b (Betaseron, Extavia)

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 9/2023

Iptacopan (Fabhalta)

Specific Therapeutic Class: *Complement Factor B Inhibitor; Complement Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Paroxysmal nocturnal hemoglobinuria

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Paroxysmal nocturnal hemoglobinuria,** approve if:
  - Patient is 18 years of age or older
  - Patient has Paroxysmal nocturnal hemoglobinuria confirmed by both of the following:
    - Flow cytometry analysis confirming presence of PNH clones
    - Documentation of laboratory results, signs, and/or symptoms attributed to PNH (e.g. LDH >1.5 × ULN, Hb <10 g/dL, abdominal pain, anemia, dyspnea, extreme fatigue, unexplained/unusual thrombosis, etc.)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a continued positive clinical response such as increased or stabilization of Hb levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc confirmed by chart notes

References: N/A

Last review/revision date: 1/2024

Isavuconazonium Sulfate (Cresemba)

Specific Therapeutic Class: *Antifungal Agent, Azole Derivative*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Aspergillosis
- Mucormycosis

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Aspergillosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has invasive disease
  - There is documentation of baseline liver function tests and liver function will be monitored during therapy
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **voriconazole**

- For the diagnosis of **Mucormycosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has invasive disease
  - There is documentation of baseline liver function tests and liver function will be monitored during therapy

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Documented response to therapy
- Additional therapy is medically necessary and clinically appropriate

References: N/A

Last review/revision date: 10/2022

Istradefylline (Nourianz)

Specific Therapeutic Class: *Anti-Parkinson Agent, Adenosine Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Parkinson's Disease

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Parkinson's Disease**, approve if:
  - Patient is 18 years of age or older
  - The requested agent will be used to treat acute, intermittent hypomobility, "off" episodes (muscle stiffness, slow movements, or difficulty starting movement) associated with advanced Parkinson's disease
  - There is evidence of a claim that the patient is receiving concurrent therapy for Parkinson's disease (e.g., levodopa, dopamine agonist, or monoamine oxidase B inhibitor) within the past 30 days
  - The requested agent is prescribed with carbidopa/levodopa
  - Prescriber is a neurologist, or the prescriber has consulted with a Neurologist

References: N/A

Last review/revision date: 9/2023

Ivacaftor (Kalydeco)

Specific Therapeutic Class: *Cystic Fibrosis Transmembrane Conductance Regulator Potentiator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cystic fibrosis

Prescribing Restriction:

- Quantity Limit*: #56 tablets or packets per 28 days
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cystic Fibrosis**, approve if:
  - Patient is 1 month of age or older
  - The patient has a diagnosis of cystic fibrosis confirmed by an FDA-approved test
  - The patient has at least one mutation in the CFTR gene that is responsive to ivacaftor confirmed by an FDA-approved test
  - The patient is NOT homozygous for the F508del mutation in the CFTR gene
  - The medication is being prescribed at a dose that is within FDA approved guidelines

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2023

Ivosidenib (Tibsovo)

Specific Therapeutic Class: *Antineoplastic Agent, IDH1 Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia
- Cholangiocarcinoma, locally advanced or metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia**, approve if:
  - Patient is 18 years of age or older
  - Patient has a susceptible IDH1 mutation confirmed by an FDA-approved test
  - One of the following:
    - Patient has relapsed or refractory disease
    - Patient has newly-diagnosed disease and one of the following:
      a. Patient is 75 years of age or older
      b. Patient has comorbidities that preclude the use of intensive induction chemotherapy

- For the diagnosis of **Cholangiocarcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has a susceptible IDH1 mutation confirmed by an FDA-approved test
  - Patient has previously treated, locally advanced, or metastatic disease

- For the diagnosis of **Off-Label Indications**, approve if:

Ivosidenib (Tibsovo)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2022

Ixazomib (Ninlaro)

Specific Therapeutic Class: *Antineoplastic Agent, Proteasome Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Multiple Melanoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Multiple Melanoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has received at least one prior chemotherapy agent
  - The requested agent will be used in combination with lenalidomide (Revlimid) and dexamethasone
  - The requested agent will not be used in combination with another proteasome inhibitor

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2022

Ixekizumab (Taltz)

Therapeutic Category: *Anti-interleukin 17A Monoclonal Antibody; Antipsoriatic Agent*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Ankylosing spondylitis
- Psoriasis
- Psoriatic arthritis
- Axial spondyloarthritis

Prescribing Restrictions:

- Quantity Limit:
  - Ankylosing spondylitis:
    - Initial: #2 (160 mg) once for 28 days
    - Maintenance #1 per 28 days thereafter
  - Plaque psoriasis:
    - Initial: #2 (160 mg) once for 14 days, then #1 (80 mg) week 2, 4, 6, 8, 10 and 12
    - Maintenance #1 per 28 days thereafter
  - Psoriatic arthritis:
    - Initial: #2 (160 mg) once for 28 days
    - Maintenance #1 per 28 days thereafter
  - Axial spondyloarthritis:
    - Initial & maintenance: #1 per 28 days
- Prescriber restriction: Rheumatologist or Dermatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID

- For diagnosis of **Axial Spondyloarthritis**, approve if:
  - Patient is 18 years of age or older

Ixekizumab (Taltz)

- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug has been prescribed by or is currently being supervised by a Rheumatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 6 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home) (Note: for patients aged 6 to 17 years of age or that have a dose of 20-40mg, administration by a healthcare professional is recommended)
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 of the following alternatives
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Ixekizumab (Taltz)

Last review/revision date: 2/2024

Ketorolac (Sprix)

Specific Therapeutic Class: *Nonsteroidal Anti-inflammatory Drug (NSAID), Nasal*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 5 days
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute pain management

Prescribing Restriction:

- Quantity Limit*: #5 bottles per 5 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pain**, approve if:
  - Patient is 17 years of age or older
  - All of the following:
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use oral ketorolac tablets
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use 2 prescription strength oral generic NSAID's, one of which is celecoxib
    - Patient has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting
  - Requested agent will be used for less than or equal to 5 days

References: N/A

Last review/revision date: 7/2022

Lanadelumab-flyo (Takhzyro)

Specific Therapeutic Class: *Kallikrein Inhibitor; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Hereditary angioedema

Prescribing Restriction:

- Quantity Limit*: #4 mL (2 vials) per 28 days
- Prescriber restriction: Prescribed by or in consultation with an allergy specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hereditary Angioedema**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of hereditary angioedema confirmed by an FDA-approved test
  - The requested agent will be used for prophylaxis of HAE attacks
  - Documentation of trial and failure with documented compliance, contraindication to, or inability to use danazol
  - Documentation of patient's weight and quantity/dose requested
  - Documentation of at least one HAE attack per month
  - The requested agent will not be used in combination with other agents for the prevention of HAE attacks

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has a documented response to therapy (reduction in HAE attacks)

References: N/A

Last review/revision date: 3/2022

Lapatinib (Tykerb)

Specific Therapeutic Class: *Antineoplastic Agent, Anti-HER2, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer, metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient is human epidermal growth factor receptor type 2 (HER2) positive confirmed by an FDA-approved test
  - Patient has advanced or metastatic disease
  - One of the following:
    - Patient has received prior therapy with an anthracycline, a taxane, and trastuzumab AND the requested agent will be used in combination with capecitabine
    - Patient is a postmenopausal woman for whom hormonal therapy is indicated AND the requested agent will be used in combination with letrozole or trastuzumab

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Lapatinib (Tykerb)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2022

Larotrectinib (Vitrakvi)

Specific Therapeutic Class: *Antineoplastic Agent, Tropomyosin Receptor Kinase (TRK) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Solid Tumors
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Solid Tumors** approve if:
  - Patient is one month of age or older
  - Patient has a neurotrophic receptor kinase (NTRK) gene fusion confirmed by an FDA-approved test
  - Patient does not have a known acquired resistance mutation
  - Patient has metastatic disease or surgical resection is likely to result in severe morbidity
  - Patient has no satisfactory alternatives or disease has progressed following previous treatment

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Ledipasvir-Sofosbuvir (Harvoni)

Specific Therapeutic Class: *Antihepaciviral, NS5A Inhibitor; Polymerase Inhibitor (Anti-HCV); NS5A Inhibitor; NS5B RNA Polymerase Inhibitor*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 24 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 3 years of age or older
  - Patient has viral genotype 1,4,5, or 6 confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glecaprevir/pibrentasvir (Mavyret)
  - If the patient has viral phenotype 4,5, or 6, the do not have decompensated cirrhosis
  - If the patient is post-liver transplant, their viral genotype is 1,4,5, or 6 confirmed by an FDA-approved test
  - If the patient is post kidney transplant, both of the following:
    - Viral genotype 1,4,5, or 6
    - They do not have decompensated cirrhosis

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Requested regimen and duration is appropriate per AASLD/IDSA guidelines

References: N/A

Last review/revision date: 8/2022

Lefamulin (Xenleta)

Specific Therapeutic Class: *Antibiotic, Pleuromutilin*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 5 days
- Continuation: N/A

Diagnosis Considered for Coverage:

- Community acquired bacterial pneumonia caused by Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae and Chlamydophila pneumoniae)

Prescribing Restriction:

- Quantity Limit*: #10 per 5 days
- Prescriber restriction: Prescribed by or in consultation with an infectious disease specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Culture and sensitivity results
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Community Acquired Bacterial Pneumonia**, approve if:
  - Patient is ≥ 18 years of age
  - Culture and Sensitivity (C&S) testing shows isolated pathogen that is susceptible to lefamulin [documentation required]: S. pneumoniae, S, aureus (methicillin-susceptible isolates), H. influenzae, L. pneumophila, M. pneumoniae and C. pneumoniae
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 4 other antibiotics for bacterial pneumonia

References: N/A

Last review/revision date: 10/2023

Lenalidomide (Revlamid)

Specific Therapeutic Class: *Angiogenesis Inhibitor; Antineoplastic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Follicular lymphoma (previously treated)
- Mantle cell lymphoma (relapsed or progressive)
- Marginal zone lymphoma (previously treated)
- Multiple myeloma
- Myelodysplastic syndromes
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Follicular Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has received at least one prior therapy
  - The requested agent will be used in combination with rituximab

- For the diagnosis of **Mantle Cell Lymphoma**, approve if:
  - Patient is 18 year of age or older
  - Patient has received therapy with bortezomib and at least one other previous therapy

- For the diagnosis of **Marginal Zone Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has received at least one prior therapy

Lenalidomide (Revlamid)

- The requested agent will be used in combination with rituximab

- For the diagnosis of **Multiple Myeloma,** approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Request is for treatment in combination with dexamethasone
    - Request is for maintenance therapy following autologous stem cell transplantation

- For the diagnosis of **Myelodysplastic Syndromes,** approve if:
  - Patient is 18 year of age or older
  - Patient has transfusion-dependent anemia
  - Patient has low- or intermediate-1-risk disease
  - Patient has a deletion 5q (del 5q) cytogenetic abnormality confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Leniolisib (Joenja)

Specific Therapeutic Class: *Phosphatidylinositol 3-Kinase (PI3K) Delta Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Activated Phosphoinositide 3-kinase Delta (PI3Kδ) Syndrome (APDS)

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Pediatrician, Immunologist, Hematologist, or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Activated Phosphoinositide 3-kinase Delta (PI3Kδ) Syndrome (APDS),** approve if:
  - Patient is 12 years of age or older
  - Patient has an APDS/PASLI-associated PIK3CD/PIK3R1 mutation without concurrent use of immunosuppressive medication confirmed by an FDA-approved test
  - There is documentation of nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g. lung, liver)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improvement in clinical signs and symptoms of APDS

References: N/A

Last review/revision date: 6/2023

Lenvatinib (Lenvima)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Endometrial carcinoma, advanced
- Hepatocellular carcinoma, unresectable
- Renal cell carcinoma, advanced
- Thyroid cancer, differentiated
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Endometrial Carcinoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease
  - The patient is not microsatellite instability-high or mismatch repair deficient confirmed by an FDA-approved test
  - Patient has received prior systemic therapy and is not a candidate for curative surgery or radiation
  - The requested agent will be used in combination with pembrolizumab

- For the diagnosis of **Hepatocellular Carcinoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has unresectable disease

Lenvatinib (Lenvima)

- For the diagnosis of **Renal Cell Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient had advanced disease
  - Patient has received at least 1 prior anti-angiogenic therapy
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sunitinib
  - The requested agent will be used in combination with everolimus

- For the diagnosis of **Thyroid Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has differentiated disease
  - Patient has locally recurrent, metastatic, or progressive disease
  - Patient is radioactive iodine-refractory

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2022

Letermovir (Prevymis)

Specific Therapeutic Class: *Antiviral Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 100 days
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cytomegalovirus (CMV) prophylaxis

Prescribing Restriction:

- Quantity Limit*:
  - #30 per 30 days
  - Maximum of 100 doses
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cytomegalovirus (CMV) Prophylaxis**, approve if:
  - The request is for the oral formulation of letermovir (Prevymis)
  - Patient is 18 years of age or older
  - The requested agent is being prescribed for prophylaxis and not treatment of CMV
  - Patient has received an allogeneic hematopoietic stem cell transplant
  - Patient is CMV-seropositive [R+]
  - The requested agent will be initiate between day 0 and 28 post-transplantation
  - There is documented inability to use valganciclovir unless the patient meets one of the following:
    - Human Leukocyte Antigen (HLA)-related (sibling) donor with at least one mismatch at one of the following three HLA-gene loci: HLA-A, -B or –DR
    - Unrelated donor with at least one mismatch at one of the following four HLA-gene loci: HLA-A, -B, -C and-DRB1
    - Haploidentical donor
    - Use of umbilical cord blood as stem cell source
    - Use of ex vivo T-cell-depleted grafts (including ex vivo use of alemtuzamab)
    - Grade 2 or greater Graft-Versus-Host Disease (GVHD) requiring systemic corticosteroids (defined as the use of ≥ 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid)
  - The patient is not currently nor will receive pimozide or ergot alkaloids
  - The patient does not have severe hepatic impairment (Child-Pugh Class C)

References: N/A

Letermovir (Prevymis)

Last review/revision date: 9/2023

Levodopa (Inbrija)

Specific Therapeutic Class: *Anti-Parkinson Agent, Dopamine Precursor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Parkinson's Disease

Prescribing Restriction:

- Quantity Limit*: #300 per 30 days
- Prescriber restriction: Prescriber is a Neurologist, or the prescriber has consulted with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Parkinson's Disease**, approve if:
  - Patient is 18 years of age or older
  - The requested agent is prescribed in combination with carbidopa/levodopa
  - The requested agent will be used to treat acute, intermittent hypomobility, "off" episodes (muscle stiffness, slow movements, or difficulty starting movement) associated with advanced Parkinson's disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Rasagiline (Azilect) AND one of the following:
    - Entacapone (Comtan/Stalevo),
    - Ropinirole/ropinirole ER (Requip/Requip XL)
    - Pramipexole/pramipexole ER (Mirapex/Mirapex ER)
    - Neupro (ritigotine)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Safinamide (Xadago)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improvement in symptoms while using the requested agent

References: N/A

Last review/revision date: 1/2023

Levoketoconazole (Recorlev)

Specific Therapeutic Class: *Cortisol Synthesis Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Endogenous hypercortisolemia associated with Cushing's Syndrome

Prescribing Restriction:

- Quantity Limit*: #240 per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cushing's Syndrome**, approve if:
  - The patient is 18 years of age or older
  - The patient has a diagnosis of endogenous Cushing's syndrome confirmed by an FDA-approved test
  - The patient does not have a diagnosis of pituitary or adrenal carcinoma
  - One of the following:
    - Documented inability for pituitary surgery
    - Patient has undergone pituitary surgery that was not curative
    - Patient has undergone pituitary surgery and has reoccurrence of symptoms
  - Documentation is submitted with baseline urinary free cortisol level
  - Documentation is submitted with a baseline QTc-interval less than 470 milliseconds
  - Patient does not have cirrhosis, acute liver disease or poorly controlled chronic liver disease, baseline AST or ALT > 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease
  - Patient does not have a history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or prolonged QT syndrome
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ketoconazole

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

Levoketoconazole (Recorlev)

- There is a documented decrease in urinary free cortisol from baseline
- Patient has not experienced an AST or ALT greater than 3x the upper limit of normal

References: N/A

Last review/revision date: 1/2022

Lofexidine (Lucemyra)

Specific Therapeutic Class: *Alpha2-Adrenergic Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 7 days
- Continuation: 7 days

Diagnosis Considered for Coverage:

- Opioid withdrawal

Prescribing Restriction:

- Quantity Limit*: #112 per 7 days
- Prescriber restriction: Prescribed by or in consultation with a physician specializing in one of the following areas: emergency medicine/inpatient care, pain management, addiction psychiatry

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Opioid Withdrawal**, approve if:
  - Patient is 18 years of age or older
  - Patient is currently or will be undergoing abrupt opioid discontinuation within the next seven days and one of the following:
    - Patient has taken one or more opioids for at least the last three weeks
    - Patient has been or will be administered an opioid antagonist (e.g., naltrexone) after a period of opioid use
  - Medical justification supports why an opioid taper (e.g., with buprenorphine, methadone or other opioid) cannot be used;
  - One of the following:
    - Documented trial and failure of clonidine unless contraindicated or clinically significant adverse effects are experienced
    - Lucemyra has already been initiated (e.g., in an inpatient/ER setting)
  - Lucemyra has not been prescribed for a prior opioid withdrawal event within the last 30 days or medical justification supports retreatment

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is currently receiving medication and has received this medication for less than 14 days
- Patient is responding positively to therapy

Lofexidine (Lucemyra)

References: N/A

Last review/revision date: 7/2022

Lomitapide (Juxtapid)

Specific Therapeutic Class: *Antilipemic Agent, Microsomal Triglyceride Transfer Protein (MTP) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Homozygous familial hypercholesterolemia

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: Prescribed by a Cardiologist, Endocrinologist, or lipid specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Homozygous Familial Hypercholesterolemia**, approve if:
  - The patient is 18 years of age or older
  - The patient has ALL of the following:
    - The patient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH), through ONE of the following:
      a. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, ARH adaptor protein 1/LDLRAP1 gene locus
      b. History of untreated LDL-C >500 mg/dL (>13 mmol/L) or treated LDL-C ≥300 mg/dL (≥7.76 mmol/L) with ONE of the following:
        i. The patient had cutaneous or tendon xanthoma before age 10 years
        ii. Untreated elevated cholesterol levels consistent with heterozygous FH in both parents [untreated LDL-C >190 mg/dL (>4.9 mmol/L) or untreated total cholesterol greater than 290 mg/dL (>7.5 mmol/L)]
    - ONE of the following:
      a. The patient is on a maximally tolerated statin containing lipid- lowering regimen (i.e., rosuvastatin in combination with ezetimibe or atorvastatin in combination with ezetimibe)
      b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL of these therapies (i.e., rosuvastatin in combination with ezetimibe and atorvastatin in combination with ezetimibe)
    - ONE of the following:
      a. The patient has tried with demonstrated adherence for at least 3 months and had an inadequate response to a PCSK9 inhibitor (e.g., Repatha, Praluent)

Lomitapide (Juxtapid)

b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL PCSK9 inhibitors

- The patient is taking daily vitamin E, linoleic acid, alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA) supplements

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improved blood lipid levels from baseline

References: N/A

Last review/revision date: 9/2023

Lonafarnib (Zokinvy)

Specific Therapeutic Class: *Farnesyltransferase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Hutchinson-Gilford progeria syndrome
- Processing-deficient progeroid laminopathies

Prescribing Restriction:

- Quantity Limit*: Quantity sufficient for a 30 day supply with a dose less than or equal to 150mg/m^2 twice daily
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Current and previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hutchinson-Gilford Progeria Syndrome**, approve if:
  - Patient is 1 year of age or older
  - Patient has a body surface area or 0.39 m^2 or higher
  - Patient does not have progeroid syndromes or processing-proficient progeroid Laminopathies

- For the diagnosis of **Processing-Deficient Progeroid Laminopathies**, approve if:
  - Patient is 1 year of age or older
  - Patient has a body surface area or 0.39 m^2 or higher
  - Patient has at least 1 of the following:
    - Heterozygous LMNA mutation with progerin-like protein accumulation
    - Homozygous or compound heterozygous ZMPSTE24 mutations
  - Patient does not have progeroid syndromes or processing-proficient progeroid Laminopathies

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Prescribed dose is less than or equal to the FDA maximum dose

References: N/A

Last review/revision date: 9/2023

Lonapegsomatropin-tcgd (Skytrofa)

Specific Therapeutic Class: *Growth Hormone*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Pediatric Growth Hormone Deficiency

Prescribing Restriction:

- Quantity Limit*: 8 cartridges per 28 days
- Prescriber restriction: Endocrinologist or Pediatrician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pediatric Growth Hormone Deficiency**, approve if:
  - Patient is 1 year of age or older
  - Patient weighs at least 11.5 kg
  - There is documentation of a subnormal GH response < 10 mg/mL by at least one provocative stimulation test (i.e., insulin-induced hypoglycemia, arginine, ARG-GHRH, ARG-LDOPA, GHRH)
  - The diagnosis has been confirmed by one of the following:
    - Severe short stature (defined as patient's height at ≥ 2 standard-deviation [SD] below the population mean)
    - Height velocity < 25th percentile
    - Patient's height ≥ 1.5 SD below the midparental height (avg of mother's and father's heights)
    - Patient's height ≥ 2 SD below the mean and a 1-year height velocity more than 1 SD below the mean for chronologic age or (in children 2 years of age or older) a 1- year decrease of more than 0.5 SD in height
    - In the absence of short stature, a 1-year height velocity more than 2 SD below the mean or a 2-year height velocity more than 1.5 SD below the mean (may occur in GHD manifesting during infancy or in organic, acquired GHD)
    - Signs indicative of an intracranial lesion
    - Signs of multiple pituitary hormone deficiencies
    - Neonatal symptoms and signs of GHD
  - Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) or patient has NOT reached final height

Lonapegsomatropin-tcgd (Skytrofa)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented response to growth hormone therapy (e.g., IGF-1 level normalization, increase in height velocity defined by >2cm/year compared to that of previous year)

References: N/A

Last review/revision date: 5/2022

Lorlatinib (Lorbrena)

Specific Therapeutic Class: *Antineoplastic Agent, Anaplastic Lymphoma Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient is anaplastic lymphoma kinase (ALK)-positive confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Lotilaner (Xdemvy)

Specific Therapeutic Class: *Antiparasitic Agent, Ophthalmic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 weeks
- Continuation: 6 weeks

Diagnosis Considered for Coverage:

- Demodex blepharitis

Prescribing Restriction:

- Quantity Limit*: #10ml per 42 days
- Prescriber restriction: Optometrist or Ophthalmologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Demodex blepharitis,** approve if:
     - Patient is 18 years of age or older
     - Patient has erythema of the upper eyelid margin confirmed by medical records
     - There is documentation of the presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination confirmed by medical records

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - Documentation is submitted supporting the need for ongoing therapy
   - There is documentation of the presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination after completing 6 weeks of initial therapy confirmed by medical records

References: N/A

Last review/revision date: 8/2023

Lumacaftor - Ivacaftor (Orkambi)

Specific Therapeutic Class: *Cystic Fibrosis Transmembrane Conductance Regulator Corrector; Cystic Fibrosis Transmembrane Conductance Regulator Potentiator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cystic fibrosis

Prescribing Restriction:

- Quantity Limit*:
  - Tablets: #112 per 28 days
  - Packets: #56 per 28 days
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Cystic Fibrosis**, approve if:
  - The patient is 2 years of age or older
  - The patient has a diagnosis of cystic fibrosis confirmed by an FDA-approved test
  - The patient is homozygous for the F508del mutation in the CFTR gene
  - The medication is being prescribed at a dose that is within FDA approved guidelines

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2022

Luspatercept (Reblozyl)

Specific Therapeutic Class: *Activin Receptor Ligand Trap; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Anemia due to beta thalassemia
- Anemia due to myelodysplastic syndromes with ring sideroblasts or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis

Prescribing Restriction:

- Quantity Limit*: Max of 1.25mg/kg once every 21 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Anemia due to Beta Thalassemia or Myelodysplastic Syndromes,** approve if:
  - The patient is 18 years of age or older
  - Patient requires regular blood transfusions
  - Hemoglobin is less than or equal to 11g/dL OR if hemoglobin is greater than 11g/dL, dosing will be delayed until it is 11g/dL or less
  - The patient is not pregnant or planning to become pregnant
  - The patient is not breastfeeding
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use an erythropoiesis stimulating agent
  - The patient has not had a recent stroke or deep vein thrombosis

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose

References: N/A

Last review/revision date: 10/2023

Lusutrombopag (Mulpleta)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent; Thrombopoietic Agent; Thrombopoietin Receptor Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 7 days
- Continuation: N/A

Diagnosis Considered for Coverage:

- Thrombocytopenia associated with chronic liver disease in patients requiring elective surgery

Prescribing Restriction:

- Quantity Limit*: #7 per 7 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. **Initiation of Therapy:**
- For the diagnosis of **Thrombocytopenia Associated with Chronic Liver Disease**, approve if:
  - The platelet level < 50,000 mm^3
  - Patient is undergoing a scheduled medical or dental procedure within the next 30 days

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2021

Macitentan (Opsumit)

Specific Therapeutic Class: *Endothelin Receptor Antagonists*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary arterial hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #30 tablets per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Pulmonary arterial hypertension (PAH),** approve if:
  - Patient has a diagnosis of PAH confirmed by RHC
  - There is documentation that the patient has WHO functional class (FC) II or III symptoms
  - The patient and prescriber have met all REMS criteria
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ambrisentan OR bosentan

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise

References: N/A

Last review/revision date: 6/2024

Macitentan-Tadalafil (Opsynvi)

Specific Therapeutic Class: *Endothelin Receptor Antagonist; Phosphodiesterase-5 Enzyme Inhibitor; Vasodilator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary arterial hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #30 tablets per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pulmonary arterial hypertension (PAH),** approve if:
  - Patient has a diagnosis of PAH confirmed by RHC
  - There is documentation that the patient has WHO functional class (FC) II or III symptoms
  - The patient and prescriber have met all REMS criteria
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use a PDE5 inhibitor plus a generic ERA (ambrisentan or bosentan)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise

References: N/A

Last review/revision date: 6/2024

Mannitol (Bronchitol)

Specific Therapeutic Class: *Mucolytic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Cystic Fibrosis

Prescribing Restriction:

- Quantity Limit*: #600/30 days (10 capsules inhaled individually via inhaler twice daily)
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cystic Fibrosis,** approve if:
  - Patient has a confirmed diagnosis of cystic fibrosis
  - Patient is 18 years of age or older
  - Patient has passed an inhaled mannitol tolerance test
  - Patient has not experienced an episode of significant hemoptysis (>60ml) in the last 3 months
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use inhaled hypertonic saline
  - The prescribed dose is less than or equal to 10 capsules inhaled via inhaler twice daily

II. Continuation of Therapy for EXISTING Members (medication filled within the last 6 months or provider attestation on PA request that member is continuing the medication), approve if:

- The patient is stable and continuing the medication
- Patient has not experienced a significant episode of hemoptysis (>60ml) since last approval
- There is documented improvement in pulmonary function
- Prescribed dose is less than or equal to the FDA maximum dose

References: N/A

Last review/revision date: 10/2023

Maralixibat (Livmarli)

Specific Therapeutic Class: *Ileal Bile Acid Transporter Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cholestatic pruritus

Prescribing Restriction:

- Quantity Limit*: #90 ml per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cholestatic Pruritus**, approve if:
  - One of the following:
    - Both of the following:
      a. Patient has a diagnosis of Alagille syndrome confirmed by an FDA-approved test
      b. Patient has cholestasis confirmed by an FDA-approved test
      c. Patient is 3 months of age or older
    - Both of the following:
      a. Patient has a diagnosis of progressive familial intrahepatic cholestasis confirmed by an FDA-approved test
      b. Patient is 5 years of age or older
  - Patient does not have a history of liver transplant
  - Patient does not have decompensated cirrhosis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following:
    - Ursodiol (ursodeoxycholic acid)
    - Cholestyramine
    - Rifampin
    - Naltrexone
    - Sertraline

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

Maralixibat (Livmarli)

- There is documentation of improvement in pruritis

References: N/A

Last review/revision date: 6/2024

Maribavir (Livtencity)

Specific Therapeutic Class: *Antiviral Agent; Benzimidazole Riboside*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 8 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cytomegalovirus

Prescribing Restriction:

- Quantity Limit*: #112 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cytomegalovirus,** approve if:
  - Patient is 12 years of age or older
  - Patient weighs greater than or equal to 35kg
  - Patient has a diagnosis of post-transplant CMV infection/disease with CMV DNA of ≥2730 IU/mL in whole blood or ≥910 IU/mL in plasma
  - Patient has a documented history of hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following: intravenous (IV) ganciclovir, valganciclovir, foscarnet, and cidofovir
  - Patient will not receive any other CMV antivirals while receiving the requested agent

References: N/A

Last review/revision date: 8/2022

Mavacamten (Camzyos)

Specific Therapeutic Class: *Cardiac Myosin Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hypertrophic cardiomyopathy with left ventricular outflow tract obstruction (HOCM)

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Cardiologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Hypertrophic Cardiomyopathy with Left ventricular Outflow Tract Obstruction (HOCM)**, approve if:
  - Patient is 18 years of age or older
  - Patient has a bodyweight of at least 45kg confirmed via medical records
  - Patient has unexplained left ventricular hypertrophy (LVH)
  - Patient has one of the following:
    - Maximal LV wall thickness greater than or equal to 15mm
    - Maximal LV wall thickness greater than or equal to 13mm and there is family history of hypertrophic cardiomyopathy (HCM)
  - Patient has a left outflow tract obstruction gradient (LVOT) greater than or equal to 50mmHg
  - Patient has a documented ejection fraction of 55% or greater
  - There is documentation that the patient is experiencing NYHA class II or III symptoms
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 rate controlling medications (beta blockers or calcium channel blockers)
  - Patient has a resting oxygen saturation of at least 90%
  - Patient does not have another diagnosis known to cause hypertrophy that mimics HOCM such as Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

Mavacamten (Camzyos)

- Patient has documented improvement in symptoms from baseline
- One of the following:
  - Patient has improvement mixed pVO2 by ≥1.5 mL/kg/min and at least one NYHA class reduction
  - Patient has pVO2 increase of ≥3.0 mL/kg/min without NYHA class worsening

References: N/A

Last review/revision date: 10/2023

Mavorixafor (Xolremdi)

Specific Therapeutic Class: *CXC Chemokine Receptor 4 (CXCR4) Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome

Prescribing Restriction:

- Quantity Limit*: #120 capsules per 30 days
- Prescriber restriction: Immunologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of WHIM syndrome confirmed by an CXCR4 genotype variant confirmed by an FDA-approved genetic test
  - There is documentation of baseline ANC and ALC to assess clinical response to treatment

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in absolute lymphocyte count (ALC) and absolute neutrophil count (ANC)

References: N/A

Last review/revision date: 6/2024

Mecamylamine (Vecamyl)

Specific Therapeutic Class: *Ganglionic Blocking Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hypertension

Prescribing Restriction:

- Quantity Limit*: #300 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a hypertension specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hypertension**, approve if:
  - Patient is 18 years of age or older
  - Patient has moderately severe to severe essential hypertension or uncomplicated malignant hypertension
  - There is documented trial and failure to maintain adequate blood pressure control despite 3 generic medications from 3 different therapeutic classes at maximally tolerated doses

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has maintained adequate hypertension control while receiving the requested agent

References: N/A

Last review/revision date: 10/2023

Mecasermin (Increlex)

Specific Therapeutic Class: *Insulin-Like Growth Factor-1, Recombinant*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Primary insulin-like growth factor-1 deficiency

Prescribing Restriction:

- Quantity Limit*: A sufficient quantity for a 30 day supply for doses up to 0.12mg/kg twice daily
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Primary Insulin-Like Growth factor-1 Deficiency**, approve if:
  - Patient is ≥ 2 and < 18 years of age
  - Somatropin (recombinant human GH) is not prescribed concurrently with the requested agent
  - Prescribed dose does not exceed 0.12 mg/kg twice daily
  - If the patient has severe primary IGF-1 deficiency (IGFD) (i.e., inherited growth hormone insensitivity), there is associated growth failure as evidenced by all of the following:
    - Basal IGF-1 is ≥ 3 standard deviations (SD) below the mean
    - Normal or elevated GH level
    - Height is ≥ 3 SD below the mean
  - If the patient has acquired GH insensitivity, all of the following:
    - Documentation of genetic GH deficiency due to a GH gene deletion
    - Documentation of presence of neutralizing GH antibodies
    - One of the following:
      a. Height > 3 SD below the mean
      b. Height > 2 SD below the mean and one of the following:
         i. Height velocity > 1 SD below the mean over 1 year
         ii. Decrease in height SD > 0.5 over 1 year in children > 2 years of age
      c. Height > 1.5 SD below midparental height
      d. Height velocity > 2 SD below the mean over 1 year
      e. Height velocity > 1.5 SD below the mean over 2 years

Mecasermin (Increlex)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented improvement in growth velocity
- Patient is <18 years of age

References: N/A

Last review/revision date: 8/2022

Mechlorethamine (Valchlor)

Specific Therapeutic Class: *Antineoplastic Agent, Alkylating Agent, Alkylating Agent (Nitrogen Mustard)*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cutaneous T-cell lymphoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cutaneous T-cell Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient stage 1A or 1B mycosis fungoides type disease
  - Patient has had prior skin directed therapy such as topical corticosteroids, topical retinoids or photo therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Mepolizumab (Nucala)

Specific Therapeutic Class: *Interleukin-5 Antagonist; Monoclonal Antibody, Anti-Asthmatic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Asthma
- Eosinophilic granulomatosis with polyangiitis
- Hypereosinophilic syndrome
- Rhinosinusitis with nasal polyps

Prescribing Restriction:

- Quantity Limit*:
  - Asthma: #1 per 28 days
  - Eosinophilic granulomatosis with polyangiitis: #3 per 28 days
  - Hypereosinophilic syndrome: #3 per 28 days
  - Rhinosinusitis with nasal polyps: #1 per 28 days
  - Prescriber restriction: Prescribed by or in consultation with a pulmonologist, immunologist, or allergist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Asthma**, approve if:
  - Patient is 6 years of age or older
  - Patient has a documented eosinophil count ≥150 cells/mcL within the past 3 months
  - Patient has experienced ≥ 2 exacerbations with in the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (ICS) plus either a long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindication/intolerance):
    - Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
    - Urgent care visit or hospital admission
    - Intubation
  - The requested agent is prescribed concomitantly with an ICS plus either a LABA or LTRA

- For the diagnosis of **Eosinophilic Granulomatosis with Polyangiitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has documentation of one of the following:
    - Eosinophil count greater than 1000 cells/mcL
    - Eosinophil count greater than 10% of the total leukocyte count

Mepolizumab (Nucala)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: systemic glucocorticoids, cyclophosphamide, azathioprine, methotrexate, leflunomide

- For the diagnosis of **Hypereosinophilic Syndrome**, approve if:
  - Patient is 12 years of age or older
  - Patient has a documented eosinophil count greater than or equal to 1000 cells/mcL
  - There are no identifiable non-hematologic secondary cause (ex: drug hypersensitivity, parasitic helminth infection, HIV infection, nonhematologic malignancy) of HES
  - Patient has experienced disease flares while stable on appropriate HES therapy such as chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy

- For the diagnosis of **Rhinosinusitis with Nasal Polyps,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 nasal corticosteroid sprays (e.g., mometasone, fluticasone, budesonide, or triamcinolone)
  - The requested agent will be used as add-on maintenance treatment

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is currently receiving medication or has previously met initial approval criteria
- There is documented adherence to therapy
- Patient is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline, reduction in the use of rescue therapy, reduction in disease flares)

References: N/A

Last review/revision date: 1/2023

Mesna (Mesnex)

Specific Therapeutic Class: *Antidote; Chemoprotective Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prevention of ifosfamide-induced hemorrhagic cystitis
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prevention of Ifosfamide-Induced Hemorrhagic Cystitis,** approve if:
  - Patient is currently receiving ifosfamide

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Methadone (Dolophine)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #180 per 30 days (up to 60 mg/day)

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the following alternatives:
    - Short-acting opiates
    - Morphine sulfate ER tablets (MS Contin) AND one other long-acting opioid at an adequate (equianalgesic) dose
  - Naloxone has also been prescribed for the patient

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Methoxy PEG-Epoetin Beta (Mircera)

Specific Therapeutic Class: *Colony Stimulating Factor; Erythropoiesis-Stimulating Agent (ESA); Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Anemia associated with chronic kidney disease (CKD)

Prescribing Restriction:

- Quantity Limit*: #2 syringes per 30 days
- Prescriber restriction: Hematologist/Oncologist, Nephrologist, Hepatologist, or Infectious Disease physician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Anemia associated with Chronic Kidney Disease (CKD)**, approve if:
  - Hemoglobin < 10g/dL
  - Patient has a confirmed diagnosis of CKD

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Hemoglobin < 12 g/dL
- Medication is used for appropriate indication and at appropriate dose
- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2021

Methylnaltrexone (Relistor)

Specific Therapeutic Class: *Gastrointestinal Agent, Miscellaneous; Opioid Antagonist, Peripherally-Acting*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Opioid induced constipation (OIC) with chronic non-cancer pain
- OIC with advanced illness

Prescribing Restriction:

- Quantity Limit*:
  - Tablets: #30 per 30 days
  - SQ:
    - 8mg/0.4ml: #12ml per 30 days
    - 12mg/0.6ml: #18ml per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Opioid Induced Constipation (OIC) with Chronic Non-Cancer pain OR with advanced illness**, approve if:
  - Patient is 18 years of age or older
  - The patient does not have a GI obstruction and is not at high risk of recurrent obstruction
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 laxatives from different classes (e.g., fiber supplements, stimulants, osmotic laxatives, etc.)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use all of the following: naloxegol (Movantik), naldemedine tosylate (Symproic), and lubiprostone (Amitiza)
  - Patient does not require frequent opioid dose escalation

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 11/2022

Metoclopramide (Gimoti)

Specific Therapeutic Class: *Prokinetic, serotonin 5-HT4 receptor agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 3 months

Diagnosis Considered for Coverage:

- Diabetic Gastroparesis

**Will not be approved for nausea and vomiting or gastroparesis in nondiabetic patients*

Prescribing Restriction:

- Quantity Limit*: 60mg/day (1 bottle per 28 days)
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Diabetic Gastroparesis**, approve if:
  - Age ≥ 18 years
  - Patient has documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to lifestyle changes (Ex: low fiber and low-fat diet, eating smaller meals more often, higher percentage of liquid calories, etc)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use erythromycin
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use oral metoclopramide (tablets or solution)
  - Dose does not exceed 60 mg per day

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is currently receiving medication or has previously met initial approval criteria
- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Metreleptin (Myalept)

Specific Therapeutic Class: *Leptin Analog*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Lipodystrophy

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Lipodystrophy**, approve if:
  - The patient has a diagnosis of leptin deficiency confirmed by an FDA-approved test
  - The patient does NOT have any of the following: partial lipodystrophy, liver disease (non-alcoholic steatohepatitis), HIV-related lipodystrophy, or generalized metabolic disease without generalized lipodystrophy
  - The patient has complications related to lipodystrophy [e.g., diabetes mellitus, hypertriglyceridemia (≥200 mg/dL), and/or high fasting insulin (≥30μU/mL)]
  - The patient has had an inadequate response to maximally tolerable conventional agent for complications related to lipodystrophy
  - The patient has had an inadequate response to lifestyle modification (i.e., diet modification and exercise) and will continue lifestyle modifications with the requested agent
  - The dose is within FDA labeled dose

References: N/A

Last review/revision date: 10/2023

Metyrosine (Demser)

Specific Therapeutic Class: *Tyrosine Hydroxylase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Pheochromocytoma (perioperative and non-perioperative)

Prescribing Restriction:

- Quantity Limit*: 16 capsules per day
- Prescriber restriction: Prescribed by or in consultation with a Cardiologist or Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Perioperative Management of Hypertension associated with Pheochromocytoma**, approve if:
  - Patient is 12 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following alternatives: doxazosin, prazosin, or terazosin
  - The prescribed quantity is less than or equal to a 14-day supply

- For the diagnosis of **Non-perioperative Management of Hypertension associated with Pheochromocytoma**, approve if:
  - Patient is 12 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following alternatives: doxazosin, prazosin, or terazosin

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose

References: N/A

Last review/revision date: 4/2022

Midostaurin (Rydapt)

Specific Therapeutic Class: *Antineoplastic Agent, FLT3 Inhibitor; Antineoplastic Agent, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia
- Mast cell leukemia
- Systemic mastocytosis
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia,** approve if:
  - Patient is 18 years of age or older
  - Patient is FLT3 mutation-positive confirmed by an FDA-approved test
  - Patient is also receiving standard induction therapy with cytarabine daunorubicin and cytarabine consolidation therapy

- For the diagnosis of **Mast Cell Leukemia,** approve if:
  - Patient is 18 years of age or older

- For the diagnosis of **Systemic Mastocytosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has aggressive systemic mastocytosis (ASM) or systemic mastocytosis with associated hematological neoplasm (SM-AHN)

Midostaurin (Rydapt)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Mifepristone (Korlym)

Specific Therapeutic Class: *Abortifacient; Antiprogestin; Cortisol Receptor Blocker*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Cushing Syndrome related hyperglycemia

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cushing's Syndrome**, approve if:
  - Patient is 18 years of age or older
  - Patient is not pregnant confirmed by an FDA-approved test
  - ONE of the following:
    - The patient has type 2 diabetes mellitus
    - The patient has glucose intolerance as defined as a 2-hr glucose tolerance test glucose value of 140-199 mg/dL
  - ONE of the following:
    - The patient has had an inadequate response to surgical resection
    - The patient is NOT a candidate for surgical resection
  - If the patient has type 2 diabetes mellitus, there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 oral or injectable antihyperglycemics

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Migalastat (Galafold)

Specific Therapeutic Class: *Pharmacologic Chaperone*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Fabry disease

Prescribing Restriction:

- Quantity Limit*: #14 per 28 days
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist or Geneticist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Fabry Disease**, approve if:
  - The patient is 18 years of age or older
  - The patient has a diagnosis of Fabry disease AND BOTH of the following:
    - The diagnosis was confirmed by mutation of alpha-galactosidase A (alpha-Gal A) gene
    - The patient has a confirmed amenable variant mutation (a complete list of amenable variants is available in the Galafold prescribing information or a specific variant can be verified as amenable at http://www.fabrygenevariantsearch.com)
  - The prescriber has assessed current levels of ALL of the following: kidney function (proteinuria, GFR), cardiac function (left ventricular hypertrophy, conduction or rhythm, mitral or aortic insufficiency), optic neuropathy, neuropathic pain, and gastrointestinal symptoms
  - ONE of the following:
    - The patient is NOT currently being treated with enzyme replacement therapy (ERT) (e.g., Fabrazyme)
    - The patient is currently being treated with ERT and will discontinue prior to starting the requested agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- The patient has had improvements and/or stabilization of at least ONE of the following while being treated with the requested agent:
  - Proteinuria
  - GFR

Migalastat (Galafold)

- Left ventricular hypertrophy
- Cardiac conduction or rhythm
- Mitral or aortic insufficiency
- Optic neuropathy
- Neuropathic pain
- Gastrointestinal symptoms

- The patient is NOT currently being treated with enzyme replacement therapy (ERT) (e.g., Fabrazyme)

References: N/A

Last review/revision date: 8/2022

Miglustat (Opfolda, Zavesca)

Specific Therapeutic Class: *Enzyme Inhibitor; Glucosylceramide Synthase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Gaucher disease
- Pompe Disease

Prescribing Restriction:

- Quantity Limit*:
  - Miglustat (Opfolda): #8 per 28 days
  - Miglustat (Zavesca): #90 per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Gaucher Disease**, approve if:
  - The patient had a diagnosis is Gaucher disease, type 1 confirmed by an FDA-approved test
  - The patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (e.g., due to allergy, hypersensitivity, or poor venous access, etc.) to use enzyme replacement therapy
  - Prescription is written for Miglustat (Zavesca)

- For the diagnosis of **Pompe Disease**, approve if:
  - The patient has a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase deficiency) confirmed by an FDA-approved test
  - The patient is 18 years of age or older
  - The patient weighs greater than or equal to 40kg
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (e.g., due to allergy, hypersensitivity, or poor venous access, etc.) to use enzyme replacement therapy
  - The requested agent will be used in combination with cipaglucosidase alfa (Pombiliti)
  - Prescription is written for Miglustat (Opfolda)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

Miglustat (Opfolda, Zavesca)

- Patient is stable and continuing the medication
- There is documented improvement in ONE of the following:
  - Spleen volume
  - Hemoglobin level
  - Liver volume
  - Platelet count
  - Growth
  - Bone pain

References: N/A

Last review/revision date: 10/2022

Mipomersen (Kynamro)

Specific Therapeutic Class: *Antihyperlipidemic Agent, Apolipoprotein B Antisense Oligonucleotide*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Homozygous familial hypercholesterolemia

Prescribing Restriction:

- Quantity Limit*: #4 ml per 28 days
- Prescriber restriction: Prescribed by a Cardiologist, Endocrinologist, or lipid specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Homozygous Familial Hypercholesterolemia**, approve if:
  - The patient is 18 years of age or older
  - The patient has ALL of the following:
    - The patient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH), through ONE of the following:
      a. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, ARH adaptor protein 1/LDLRAP1 gene locus
      b. History of untreated LDL-C >500 mg/dL (>13 mmol/L) or treated LDL-C ≥300 mg/dL (≥7.76 mmol/L) with ONE of the following:
        i. The patient had cutaneous or tendon xanthoma before age 10 years
        ii. Untreated elevated cholesterol levels consistent with heterozygous FH in both parents [untreated LDL-C >190 mg/dL (>4.9 mmol/L) or untreated total cholesterol greater than 290 mg/dL (>7.5 mmol/L)]
    - ONE of the following:
      a. The patient is on a maximally tolerated statin containing lipid- lowering regimen (i.e., rosuvastatin in combination with ezetimibe or atorvastatin in combination with ezetimibe)
      b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL of these therapies (i.e., rosuvastatin in combination with ezetimibe and atorvastatin in combination with ezetimibe)
    - ONE of the following:
      a. The patient has tried with demonstrated adherence for at least 3 months and had an inadequate response to a PCSK9 inhibitor (e.g., Repatha, Praluent)

Mipomersen (Kynamro)

b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL PCSK9 inhibitors

- The patient will NOT be receiving apheresis while on therapy

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improved blood lipid levels from baseline

References: N/A

Last review/revision date: 10/2023

Mirikizumab-mrkz (Omvoh)

Therapeutic Category: *Interleukin-23 Inhibitor; Monoclonal Antibody*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Ulcerative colitis

Prescribing Restrictions:

- Quantity Limit:
  - Ulcerative Colitis
    - Initial (after IV induction): 200 mg at week 12
    - Maintenance: 200 mg every 4 weeks
- Prescriber restriction: Gastroenterologist

Clinical Information Required for Review:

- Medical records
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 1/2024

Mitapivat (Pyrukynd)

Specific Therapeutic Class: *Pyruvate Kinase Activator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Hemolytic anemia

Prescribing Restriction:

- Quantity Limit*: #56 per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hemolytic Anemia**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of pyruvate kinase deficiency confirmed by an FDA-approved test
  - Patient has at least two mutant alleles in the *PKLR* gene, with at least one being a missense mutation, confirmed by an FDA-approved genetic test
  - Patient is not homozygous for the R479H mutation and does not have two non-missense variants (unless there is an additional missense mutation in the *PKLR* gene) confirmed by an FDA-approved genetic test
  - Patient has required at least 6 red blood cell (RBC) transfusions in the previous year
  - Patient's hemoglobin is less than or equal to 10mg/dL
  - Patient will also be taking at least 1 mg of folic acid concomitantly with the requested agent confirmed via prescription records
  - Patient is not currently and will not be receiving hematopoietic-stimulating agents while taking the requested agent
  - Patient does not have moderate or severe hepatic dysfunction

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient's hemoglobin is less than 14mg/dL
- One of the following:
  - Patient's hemoglobin has increased at least 1.5mg/dL from baseline
  - Patient has a documented reduction in RBC transfusions from baseline

Mitapivat (Pyrukynd)

References: N/A

Last review/revision date: 3/2022

Mitotane (Lysodren)

Specific Therapeutic Class: *Antineoplastic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Adrenocortical carcinoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Adrenocortical Carcinoma,** approve if:
  - Patient is 18 years of age or older
  - The tumor is inoperable

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Mobocertinib (Exkivity)

Specific Therapeutic Class: *Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*

Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer, locally advanced or metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutations confirmed by an FDA-approved test
  - Patient's disease has progressed on or after platinum-based chemotherapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Mobocertinib (Exkivity)

References: N/A

Last review/revision date: 10/2023

Momelotinib (Ojjaara)

Specific Therapeutic Class: *Antineoplastic Agent, Activin A Receptor Type 1 Inhibitor; Tyrosine Kinase Inhibitor; Janus Associated Kinase Inhibitor; Janus Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Myelofibrosis
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Myelofibrosis,** approve if:
  - Patient is 18 years of age or older
  - Patient has intermediate or high-risk primary or secondary (postpolycythemia vera or postessential thrombocythemia) myelofibrosis confirmed by an FDA-approved test
  - Patient has anemia confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Momelotinib (Ojjaara)

Last review/revision date: 10/2023

Monomethyl Fumarate (Bafiertam)

Specific Therapeutic Class: Fumaric Acid Derivative
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
  - Will not be used in combination with any other disease-modifying MS agent

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
  - Will not be used in combination with any other disease-modifying MS agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Monomethyl Fumarate (Bafiertam)

Last review/revision date: 10/2023

Morphine ER (Arymo ER, Kadian, MorphBond ER, MS Contin)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - If request is within quantity limits, approve

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Morphine IR

Standard/Specific Therapeutic Class: *Narcotic Analgesics*

Formulary Status:

- Formulary
  - Morphine sulfate (MS-IR) tablet
  - Morphine sulfate 10, 20, 100 mg/5 ml solution
  - Morphine sulfate 5, 20, 20, 30 mg suppository

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain

Morphine IR

- Indication of chronic cancer pain
- There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
- There is documented failure despite compliance to long-acting opiates
- Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Nafarelin (Synarel)

Specific Therapeutic Class: *Gonadotropin Releasing Hormone Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Central precocious puberty
- Endometriosis

Prescribing Restriction:

- Quantity Limit*: #24 ml per 22 days
- Prescriber restriction: See below for indication-specific prescribing criteria

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Central Precocious Puberty**, approve if:
  - Diagnosis of central Precocious Puberty confirmed by ALL of the following:
    - Elevated basal luteinizing hormone (LH) level > 0.2 -0.3 mIU/L OR elevated leuprolide-stimulated LH level >3.3-5 IU/l
    - Difference between bone age and chronological age was > 1 year
    - Age at onset of sex characteristics is <8 years if female or <9 years if male
  - If female, member is 2-11 years of age
  - If male, member is 2-12 years of age
  - Member is not pregnant
  - Dose is no more than 1800mcg per day
  - Prescribed by or in consultation with a pediatric Endocrinologist

- For the diagnosis of **Endometriosis**, approve if:
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use two analgesics (ibuprofen, meloxicam, naproxen, etc.)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use combined oral contraceptive or progestin
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use an oral or injectable GnRH agonist
  - Patient is premenopausal

Nafarelin (Synarel)

- Prescribed by or in consultation with an Obstetrics/Gynecologist or reproductive Endocrinologist
- The patient is 18 years of age or older
- The patient is not pregnant

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 2/2022

Naloxegol (Movantik)

Specific Therapeutic Class: *Gastrointestinal Agent, Miscellaneous; Opioid Antagonist, Peripherally-Acting*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Opioid induced constipation (OIC) with chronic non-cancer pain
- OIC with chronic pain related to prior cancer or its treatment who do not require frequent (ex: weekly) opioid dosage escalation

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Opioid Induced Constipation (OIC) with Chronic Non-Cancer Pain OR with previous or current Cancer-Related Pain and does not require frequent dose adjustment**, approve if:
  - Patient is 18 years of age or older
  - The patient does not have a GI obstruction and is not at high risk of recurrent obstruction
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 laxatives from different classes (e.g., fiber supplements, stimulants, osmotic laxatives, etc.
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use both: naldemedine tosylate (Symproic) and lubiprostone (Amitiza)
  - Patient does not require frequent opioid dose escalation

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 11/2022

Naloxone Auto-Injector (Evzio)

Specific Therapeutic Class: *Antidote; Opioid Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Risk for Opioid Overdose

Prescribing Restriction:

- Quantity Limit*: #1 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Risk for Opioid Overdose**, approve if:
  - Patient has ONE of the following risk factors for opioid overdose:
    - History of opioid overdose
    - History of substance use disorder
    - The patient is receiving ≥ 50 morphine milligram equivalents (MME) per day
    - The patient is concomitantly using opioids with another Central Nervous System (CNS) depressant (e.g., benzodiazepines, alcohol, or muscle relaxants)
    - The prescriber has provided documentation of another risk factor
  - ONE of the following:
    - The patient has a documented inability to use generic naloxone injection AND Narcan Nasal Spray
    - The patient has an FDA labeled contraindication, intolerance, or hypersensitivity to generic naloxone injection AND Narcan Nasal Spray that is not expected to occur with the requested agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Nedosiran (Rivfloza)

Therapeutic Category: *Lactate Dehydrogenase A (LDHA)-Directed Small Interfering Ribonucleic Acid (siRNA)*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Primary hyperoxaluria type 1

Prescribing Restrictions:

- Quantity Limit: #1 syringe or 2 vials per 28 days
- Prescriber restriction: Nephrologist or Urologist

Clinical Information Required for Review:

- Diagnosis and severity
- Medical records
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Primary Hyperoxaluria Type 1,** approve if:
  - Patient is 9 years of age or older
  - Patient has diagnosis of primary hyperoxaluria type 1 confirmed by an AGXT mutation via genetic testing or liver enzyme analysis
  - Patient has an eGFR ≥30 mL/min/1.73 m^2
  - Patient has a 24-hour urinary oxalate excretion ≥0.7 mmol normalized to 1.73 m^2 BSA
  - Patient has not had a kidney or liver transplant
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use pyridoxine

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvement in urinary or plasma oxalate levels

References: N/A

Last review/revision date: 6/2024

Neratinib (Nerlynx)

Specific Therapeutic Class: *Antineoplastic Agent, Anti-HER2, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast Cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Patient has early stage disease and has been previously treated with trastuzumab
    - Patient has advanced disease, and the requested agent will be used in combination with capecitabine
    - Patient has metastatic disease, the requested agent will be used in combination with capecitabine, and the patient has previously received at least two anti-HER2-based regimens
  - Patient is human epidermal growth factor receptor 2 (HER2)-positive confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Neratinib (Nerlynx)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Newly Approved Medications/New Indications

Formulary Status: Non-formulary

Coverage Duration: 6 months

Diagnosis Considered for Coverage:

- All FDA-approved indications without specifically defined criteria

Prescribing Restriction

- Quantity Limit*: Not to exceed a quantity equivalent to the FDA-approved maximum dose for the requested indication

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- For **Newly Approved Medications and New Indications,** approve if:
  - No criteria is currently available for the requested indication (otherwise follow specific criteria)
  - Patient meets appropriate diagnostic criteria for the disease or condition for which the medication is being requested to treat
  - The proposed use for the requested agent is an FDA-approved indication
  - Patient has documented trial and failure or inability to use appropriate standard of care or step therapies as defined in the FDA-approved indication for use
  - Patient does not have any contraindications to therapy as described in the FDA-approved prescribing information
  - The prescribed dose and quantity are within the FDA-approved dosing range

References: N/A

Last review/revision date: 1/2023

Nilotinib (Tasigna)

Specific Therapeutic Class: *Antineoplastic Agent, BCR-ABL Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic myelogenous leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Myelogenous Leukemia,** approve if:
  - Patient is 1 year of age or older
  - One of the following
    - Request is for treatment of newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia (CML) in chronic phase
    - Request is for treatment of chronic- and accelerated-phase Philadelphia chromosome-positive CML and both of the following:
      a. Patient is 18 years of age or older
      b. Patient has received prior therapy that included imatinib
    - Request is for treatment of chronic phase Philadelphia chromosome-positive CML with resistance or intolerance to prior tyrosine-kinase inhibitor therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)

Nilotinib (Tasigna)

- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Nintedanib (Ofev)

Specific Therapeutic Class: *Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Idiopathic pulmonary fibrosis
- Chronic fibrosing interstitial lung diseases with a progressive phenotype
- Systemic sclerosis-associated interstitial lung disease

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Pulmonologist or Rheumatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Idiopathic pulmonary fibrosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of Idiopathic pulmonary fibrosis confirmed by all of the following:
    - Physical exam
    - FVC<82% of predicted
    - TLC<80% of predicted
    - CT with classic findings of usual interstitial pneumonitis (UIP)
  - There are no known causes of the patients interstitial lung disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability to use pirfenidone (Esbriet)

- For the diagnosis of **Chronic fibrosing interstitial lung diseases with a progressive phenotype**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of chronic fibrosing interstitial lung diseases with a progressive phenotype confirmed by all of the following:
    - Patient has a progressive phenotype
    - FVC ≥45% of predicted
    - DLCO 30-79% of predicted

- For the diagnosis of **Systemic sclerosis-associated interstitial lung disease,** approve if:
  - Patient is 18 years of age or older

Nintedanib (Ofev)

- Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease confirmed by all of the following:
  - FVC ≥40% of predicted
  - DLCO 30-89% of predicted

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of patient improvement based on a slowed the rate of decline of lung function, improved (or no decline in) symptoms of cough or shortness of breath or improved sense of well-being

References: N/A

Last review/revision date: 9/2022

Niraparib (Zejula)

Specific Therapeutic Class: *Antineoplastic Agent, PARP Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Ovarian, fallopian tube, or primary peritoneal cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer,** approve if:
  - Patient is 18 years of age or older
  - One of the following
    - Patient has recurrent disease and has previously had a complete or partial response to platinum-based chemotherapy
    - Patient has advanced disease and has previously had a complete or partial response to first-line platinum-based chemotherapy
    - Patient has advanced disease and both of the following:
      a. Previously treated with at least three prior chemotherapy regimens
      b. Patient is homologous recombination deficiency (HRD) positive status confirmed by an FDA-approved test and one of the following:
         i. Patient has a deleterious or suspected deleterious BRCA mutation
         ii. Patient has genomic instability and has progressed more than six months after response to the last platinum-based chemotherapy

- For the diagnosis of **Off-Label Indications**, approve if:

Niraparib (Zejula)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Niraparib-Abiraterone (Akeega)

Specific Therapeutic Class: *Antiandrogen; Antineoplastic Agent; PARP Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prostate Cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Quantity Limit: Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prostate Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic, castration-resistant disease
  - Patient has a deleterious or suspected deleterious BRCA-mutation confirmed by an FDA-approved test
  - Requested agent will be used in combination with prednisone

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2023

Nirogacestat (Ogsiveo)

Specific Therapeutic Class: *Antineoplastic Agent, Gamma Secretase Inhibitor; Gamma Secretase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Desmoid tumors
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **desmoid tumors,** approve if:
  - Patient has a diagnosis of desmoid tumors confirmed by an FDA-approved test
  - There is documentation of tumor progression
  - Patient is 18 years of age or older

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2024

Nitisinone (Orfadin and Nityr)

Specific Therapeutic Class: *4-Hydroxyphenylpyruvate Dioxygenase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hereditary tyrosinemia type 1

Prescribing Restriction:

- Quantity Limit*: 2mg/kg/day
- Prescriber restriction: Specialist in inherited metabolic disorders

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hereditary Tyrosinemia Type 1**, approve if:
  - Diagnosis is confirmed by an FDA-approved DNA test OR by detection of succinylacetone (SA) in the urine
  - There is documentation provided attesting to diet restricting tyrosine and phenylalanine
  - If the request is for nitisinone (Orfadin) capsules or suspension, there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic Nitisinone tablets

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable or improving and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 8/2022

Obeticholic Acid (Ocaliva)

Specific Therapeutic Class: *Farnesoid X Receptor Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Primary biliary cholangitis

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescriber must be a Hepatologist or Gastroenterologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Primary Biliary Cholangitis**, approve if:
  - Patient is 18 years of age or older
  - Patient does not have complete biliary obstruction
  - One of the following:
    - Patient does not have cirrhosis
    - Patient has compensated cirrhosis with no evidence of portal hypertension
  - One of the following:
    - Patient has had an inadequate response to ursodiol, and the requested agent will be used in combination with ursodiol
    - Patient was unable to tolerate ursodiol and the requested agent will be used as monotherapy

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 8/2022

Octreotide (Bynfezia, Mycapssa)

Specific Therapeutic Class: *Antidiarrheal; Antidote; Somatostatin Analog*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Acromegaly
- Carcinoid syndrome (Injection only)
- Gastroenteropancreatic neuroendocrine tumors, functional, vasoactive intestinal peptide-secreting (injection only)

Prescribing Restriction:

- Quantity Limit*:
  - Oral Capsules: #56 per 28 days
  - Injectable: #45ml per 30 days
- Prescriber restriction: Prescriber is an Endocrinologist or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acromegaly**, approve if:
  - Patient's diagnosis is confirmed by one of the following:
    - Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
    - Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis
  - If the prescription is written for the octreotide oral capsules (Mycapssa), there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use injectable octreotide

- For the diagnosis of **Carcinoid Syndrome (Injection only)**, approve if:
  - Patient has a metastatic gastroenteropancreatic neuroendocrine tumor (GEP-NET) confirmed by an FDA-approved test
  - The prescription is written for injectable octreotide

- For the diagnosis of **Gastroenteropancreatic Neuroendocrine Tumors (injection only)**, approve if:
  - The patient has vasoactive intestinal peptide-secreting GEP-NETs (VIPomas) confirmed by an FDA-approved test
  - The prescription is written for injectable octreotide

Octreotide (Bynfezia, Mycapssa)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- If the patient has Acromegaly, the patient's IGF-1 level has decreased or normalized from baseline

References: N/A

Last review/revision date: 4/2022

Odevixibat (Bylvay)

Standard/Specific Therapeutic Class: *Ileal Bile Acid Transporter Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Re-authorization: 12 months

Diagnosis Considered for Coverage:

- Progressive familial intrahepatic cholestasis (PFIC)
- Other diagnoses: see off-label criteria

Prescribing Restriction:

- Quantity Limit*: 6mg/day

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information required for Review:

- Diagnosis
- Previous and current therapy
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Progressive Familial Intrahepatic Cholestasis (PFIC),** approve if:
  - Patient is 3 months of age or older
  - Diagnosis is confirmed by an FDA-approved molecular genetic test
  - Genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3
  - Patient has moderate to severe pruritis and drug-induced pruritis has been ruled out
  - Patient does not have a history of liver transplant
  - Patient does not have a history of biliary diversion surgery within the past 6 months
  - Patient does not have decompensated cirrhosis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ursodiol OR patient will have concurrent use of ursodiol while on therapy with the requested agent
  - Patient will not be taking more than one dosage form at a time (ex-capsules, pellets)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- There is documentation of improvement in pruritus
- Patient has not experienced clinically significant portal hypertension or decompensated cirrhosis

Odevixibat (Bylvay)

- One of the following:
  - There is documentation of bile acid level less than or equal to 70 micromol per liter
  - There is documentation of a reduction in bile acid by at least 70% from baseline

References: N/A

Last review/revision date: 8/2022

Ofatumumab (Kesimpta)

Specific Therapeutic Class: Anti-CD20 Monoclonal Antibody; Antineoplastic Agent
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*:
  - Initial: #1.2ml per 28 days
  - Subsequent fills: #0.4ml per 28 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - Patient does not currently have a hepatitis B infection

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - Patient does not currently have a hepatitis B infection

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Off-Label Uses

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology, and/or positive results from two peer-reviewed published studies.

Prescribing Restriction

- Quantity Limit*: not to exceed common off-label dose or dose used in published trials

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- For off-label indications, approve if:
  - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia
  - One of the following:
    - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR
    - Requested use can be supported by at least two published peer reviewed clinical studies

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 12/2022

Olaparib (Lynparza)

Specific Therapeutic Class: *Antineoplastic Agent, PARP Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer
- Ovarian cancer, advanced, refractory, recurrent
- Pancreatic cancer, metastatic
- Prostate cancer, metastatic, castration-resistant
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer,** approve if:
  - Patient is 18 year of age or older
  - Patient has metastatic disease
  - Patient has a deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) confirmed by an FDA-approved test
  - Patient is HER2-negative confirmed by an FDA-approved test
  - Patient has received prior chemotherapy in the neoadjuvant, adjuvant, or metastatic setting
  - If the patient is HR-positive confirmed by an FDA-approved test, they meet one of the following:
    - Patient has been treated with prior endocrine therapy
    - Patient is considered to be an inappropriate candidate for endocrine therapy

- For the diagnosis of **Ovarian Cancer,** approve if:
  - Patient is 18 years of age or older

Olaparib (Lynparza)

- One of the following:
  - All of the following:
    a. Patient has advanced disease
    b. One of the following:
      i. Both of the following
        1. Patient has a BRCA-positive mutation confirmed by an FDA-approved test
        2. Patient has had at least 3 prior lines of chemotherapy
      ii. Both of the following
        1. Patient has had a complete or partial response to platinum-based chemotherapy
        2. One of the following:
          a. Patient has a BRCA-positive mutation confirmed by an FDA approved test
          b. The requested agent will be used in combination with bevacizumab and the disease is associated with a homologous recombination deficiency (HRD) positive status
  - Both of the following:
    a. Patient has recurrent disease
    b. Patient has had a complete or partial response to platinum-based chemotherapy

- For the diagnosis of **Pancreatic Cancer,** approve if:
  - Patient is 18 year of age or older
  - Patient has metastatic disease
  - Patient has a deleterious or suspected deleterious germline BRCA-mutation confirmed by an FDA-approved test
  - Patients disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

- For the diagnosis of **Prostate Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation confirmed by an FDA-approved test
  - Disease is metastatic
  - Disease is castration resistant
  - Patient's disease has progressed following prior treatment with enzalutamide or abiraterone
  - Patent has had a bilateral orchiectomy or patient will be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently with the requested agent

Olaparib (Lynparza)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Olutasidenib (Rezlidhia)

Specific Therapeutic Class: *Antineoplastic Agent, IDH1 Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia, relapsed or refractory
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute Myeloid Leukemia,** approve if:
  - Patient is 18 years of age or older
  - Patient has relapsed or refractory disease
  - Patient has a susceptible isocitrate dehydrogenase-1 mutation confirmed by an FDA-approved test

- For the diagnosis of O**ff-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 12/2022

Omacetaxime (Synribo)

Specific Therapeutic Class: *Antineoplastic Agent, Cephalotaxine, Protein Synthesis Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic myeloid leukemia (CML)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Myeloid Leukemia**, approve if:
  - Patient is 18 years of age or older
  - Disease is in chronic or accelerated phase
  - Patient is resistant or intolerant to at least 2 tyrosine kinase inhibitors

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Omalizumab (Xolair)

Specific Therapeutic Class: *Monoclonal Antibody, Anti-Asthmatic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Asthma
- Chronic spontaneous urticaria
- Nasal polyps
- IgE-mediated food allergy

Prescribing Restriction:

- Quantity Limit*:
  - Asthma: #6ml per 28 days
  - Chronic Idiopathic Urticaria (CIU): #2ml per 28 days
  - Nasal Polyps: #8ml per 28 days
  - IgE-mediated food allergy: #8ml per 28 days
- Prescriber restriction: See indication-based prescriber restrictions below

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Asthma**, approve if:
  - Patient is ≥ 6 years of age
  - Diagnosis of moderate to severe persistent asthma confirmed by an FDA-approved test
  - Patient has experienced ≥ 2 exacerbations, within the last 12 months, requiring any of the following despite adherent use of controller therapy for at least 6 months (i.e., medium- to high-dose inhaled corticosteroid (ICS) plus either a long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindicated/intolerance):
    - Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
    - Urgent care visit or hospital admission
    - Intubation
  - There is documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen
  - Immunoglobulin E (IgE) level ≥ 30 IU/mL
  - Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
  - The requested agent is prescribed concomitantly with an ICS plus either a LABA or LTRA

- For the diagnosis of **Chronic spontaneous urticaria**, approve if:
  - Diagnosis of CIU confirmed by an FDA-approved test

Omalizumab (Xolair)

- Patient is ≥ 12 years of age
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use both of the following:
  - Two antihistamines (including one second generation antihistamine – e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) at maximum indicated doses, each used for ≥ 2 weeks
  - A LTRA in combination with an antihistamine at maximum indicated doses for ≥ 2 weeks
- Prescribed by or in consultation with a dermatologist, immunologist, or allergist

- For the diagnosis of **Nasal polyps**, approve if:
  - Patient is 18 years of age or older
  - Patient has a baseline serum IgE level between 30 – 1500 IU/ml
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 nasal sprays
  - The requested agent will be used as add-on therapy

- For the diagnosis of **IgE-mediated food allergy**, approve if:
  - Patient is 1 year of age or older
  - Patient has a diagnosis of IgE-mediated food allergy confirmed by a positive skin prick test or positive serum IgE test
  - Patient has a documented clinical history of IgE-mediated allergy to one or more foods
  - Prescribed by or in consultation with an Allergist or Immunologist

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For Asthma
  - Demonstrated continued adherence to asthma controller therapy that includes an ICS plus either an LABA or LTRA
  - Member is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second) since baseline, reduction in the use of rescue therapy)
- For UIC and nasal polyps
  - Patient is responding positively to therapy

References: N/A

Last review/revision date: 10/2023

Omaveloxolone (Skyclarys)

Specific Therapeutic Class: *Nuclear Factor Erythroid 2-Related Factor 2 Activator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Friedreich ataxia

Prescribing Restriction:

- Quantity Limit*: #90 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist or Cardiologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Friedreich Ataxia,** approve if:
  - Patient is 16 years of age or older
  - Patient's diagnosis is confirmed by an FDA-approved genetic test
  - There is documentation of an MRI of the brain to rule out other causes of ataxia

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of the need for continued therapy

References: N/A

Last review/revision date: 10/2023

Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir (Viekira Pak)

Specific Therapeutic Class: *Antihepaciviral, NS3/4A Protease Inhibitor (Anti-HCV); NS5A Inhibitor; Polymerase Inhibitor (Anti-HCV); Cytochrome P-450 Inhibitor; NS3/4A Inhibitor; NS5B RNA Polymerase Inhibitor*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 24 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)

Prescribing Restriction:

- Quantity Limit*: #112 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 18 years of age or older
  - Patient has viral genotype 1or 4 confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glecaprevir/pibrentasvir (Mavyret)
  - The patient does not have decompensated cirrhosis

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Requested regimen and duration is appropriate per AASLD/IDSA guidelines

References: N/A

Last review/revision date: 8/2022

Osilodrostat (Isturisa)

Specific Therapeutic Class: *Cortisol Synthesis Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cushing disease

Prescribing Restriction:

- Quantity Limit*: #180 per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cushing Disease**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Documented inability for pituitary surgery
    - Patient has undergone pituitary surgery that was not curative
    - Patient has undergone pituitary surgery and has reoccurrence of symptoms
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least one of the following alternatives: cabergoline or temozolomide

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose

References: N/A

Last review/revision date: 10/2023

Osimertinib (Tagrisso)

Specific Therapeutic Class: *Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Both of the following
      a. Patient has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations confirmed by an FDA-approved test
      b. One of the following:
        i. Requested agent will be used for first-line treatment of metastatic disease
        ii. Requested agent will be used for adjuvant therapy after tumor resection
    - All of the following
      a. Patient is epidermal growth factor receptor (EGFR) T790M mutation-positive confirmed by an FDA-approved test
      b. Patient has not been previously treated with osimertinib (Tagrisso)
      c. Disease is metastatic
      d. Patient has experienced disease progression after tyrosine kinase inhibitor therapy

Osimertinib (Tagrisso)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Oteseconazole (Vivjoa)

Specific Therapeutic Class: *Antifungal Agent, Azole Derivative*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Vulvovaginal candidiasis, recurrent

Prescribing Restriction:

- Quantity Limit*: #18 per 84 days
- Prescriber restriction: Prescribed by or in consultation with an infectious disease specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Vulvovaginal Candidiasis,** approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of vulvovaginal candidiasis confirmed by FDA-approved test/culture
  - Patient has experienced at least 3 culture-confirmed episodes of vulvovaginal candidiasis in the past 12 months confirmed by medical records
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use oral fluconazole
  - If the patient has an allergy to fluconazole or if there is documented resistance to fluconazole, there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Ibrexafungerp
  - Patient is not pregnant or lactating

References: N/A

Last review/revision date: 10/2023

Oxybate Salts (Xywav)

Specific Therapeutic Class: *Central Nervous System Depressant*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Narcolepsy with excessive daytime sleepiness
- Narcolepsy with cataplexy
- Idiopathic hypersomnia

Prescribing Restriction:

- Quantity Limit*: #540 ml per 30 days
- Prescriber restriction: Prescriber is a Neurologist or sleep specialist, or documentation has been provided that prescriber has consulted with a Neurologist or sleep specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Narcolepsy with Excessive Daytime Sleepiness**, approve if:
  - Patient is ≥ 7 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two stimulants
  - One of the following:
    - Documentation of trial and failure with documented compliance, intolerance, or contraindication (i.e., drug interaction, allergy, adverse reaction, etc.) to use Xyrem
    - Inability to use Xyrem due to one or more of the following conditions:
      a. Uncontrolled hypertension
      b. Heart Failure
      c. Significant liver disease
      d. Chronic Kidney Disease stage III or IV

- For the diagnosis of **Narcolepsy with Cataplexy,** approve if:
  - Patient is ≥ 7 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy

Oxybate Salts (Xywav)

- If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two formulary stimulants and at least two of the following: SSRI, formulary TCA, or venlafaxine
- One of the following:
  - Documentation of trial and failure with documented compliance, intolerance, or contraindication (i.e., drug interaction, allergy, adverse reaction, etc.) to use Xyrem
  - Inability to use Xyrem due to one or more of the following conditions:
    a. Uncontrolled hypertension
    b. Heart Failure
    c. Significant liver disease
    d. Chronic Kidney Disease stage III or IV

- For the diagnosis of **Idiopathic Hypersomnia**, approve if:
  - Patient is ≥ 18 years of age
  - The diagnosis has been confirmed by polysomnography and a multiple sleep latency test
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following:
    - Modafinil
    - Armodafinil
    - Methylphenidate

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Documentation has been submitted indicating patient has clinically benefited from treatment (i.e., improvement on Epworth Sleepiness score or other documentation)
- For cataplexy, documentation has been provided that there has been a reduction in frequency of cataplexy attacks.

References: N/A

Last review/revision date: 10/2023

Oxycodone ER (Oxycontin, Xtampza ER)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*

Formulary Status:

- Formulary:
  - Oxycodone ER (Oxycontin)
- Non-formulary:
  - Oxycodone ER (Xtampza ER)

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For oxycodone ER (Xtampza ER), there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use oxycodone ER (Oxycontin)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Oxycodone IR (Roxicodone)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*

Formulary Status:

- Formulary
  - Oxycodone tablet
  - Oxycodone 5 mg/5 ml solution
  - Oxycodone 20 mg/ml oral concentrate

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days for tablets*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain

Oxycodone IR (Roxicodone)

- Indication of chronic cancer pain
- There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
- There is documented failure despite compliance to long-acting opiates
- Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Oxycodone-Acetaminophen (Percocet, Primlev, Roxicet)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*

Formulary Status:

- Formulary
  - Oxycodone/acetaminophen (Percocet) 2.5-325, 5-325, 7.5-325, 10-325 mg tablet
  - Oxycodone/acetaminophen 5-325 mg/5 ml solution (Roxicet)
- Non-Formulary
  - Oxycodone/APAP 5/300, 7.5/300, 10/300 mg tab (Primlev)

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 tablets per 30 days*
  - Non-formulary drug: for duration requested up to one year

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

Oxycodone-Acetaminophen (Percocet, Primlev, Roxicet)

- For requests for formulary medication over subsequent fill quantity limit, approve if:
  - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
  - Indication of chronic cancer pain
  - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
  - There is documented failure despite compliance to long-acting opiates
  - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Oxycodone-Aspirin (Endodan)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status:

- Formulary
  - Oxycodone/aspirin 4.8355-325 mg tablet

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
    - Indication of chronic cancer pain
    - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)

Oxycodone-Aspirin (Endodan)

- There is documented failure despite compliance to long-acting opiates
- Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Oxymorphone (Opana)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
    - Indication of chronic cancer pain
    - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
    - There is documented failure despite compliance to long-acting opiates
    - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

Oxymorphone (Opana)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Oxymorphone ER (Opana ER)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ALL of the following alternatives at an adequate (equianalgesic) dose
    - Oxymorphone immediate release
    - Morphine sulfate ER tablets (MS Contin) or capsules (Kadian)
    - Fentanyl patches (Duragesic) AND Oxycodone ER (Oxycontin)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Ozanimod (Zeposia)

Specific Therapeutic Class: *Sphingosine 1-Phosphate (S1P) Receptor Modulator*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)
- Ulcerative colitis

Prescribing Restriction:

- Quantity Limit*:
  - Initial: #37 per 30 days
  - All subsequent fills: #30 per 30 days
- Prescriber restriction: Neurologist, Gastroenterologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - Drug is being prescribed by a Neurologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
  - Will not be used in combination with any other disease-modifying MS agent
  - Patient has not experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months
  - Patient does not have Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
  - Patient does not have severe untreated sleep apnea

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - Drug is being prescribed by a Neurologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate

Ozanimod (Zeposia)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
- Will not be used in combination with any other disease-modifying MS agent
- Patient has not experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months
- Patient does not have Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
- Patient does not have severe untreated sleep apnea

- For the diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Drug is being prescribed by a Gastroenterologist
  - Patient has not experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months
  - Patient does not have Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
  - Patient does not have severe untreated sleep apnea
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2024

Pacritinib (Vonjo)

Specific Therapeutic Class: *Antineoplastic Agent, FLT3 Inhibitor, Janus Associated Kinase Inhibitor, Tyrosine Kinase Inhibitor*

Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Myelofibrosis

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Hematologist or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Myelofibrosis,** approve if:
  - Patient is 18 years of age or older
  - Patient has intermediate or high-risk primary or secondary (postpolycythemia vera or postessential thrombocythemia) myelofibrosis confirmed by an FDA-approved test
  - Patient has splenomegaly confirmed by physical exam
  - Patient has documentation of severe thrombocytopenia defined as a platelet count <50,000/mm^3
  - Patient does not have any signs or symptoms of active bleeding

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented improvement in spleen volume and patient symptoms from baseline
- The patient has been compliant with therapy confirmed by medication fill history

References: N/A

Last review/revision date: 10/2023

Palbociclib (Ibrance)

Specific Therapeutic Class: *Antineoplastic Agent, Cyclin-Dependent Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - Disease is advanced or metastatic
  - Patient is hormone receptor (HR) positive confirmed by an FDA-approved test
  - Patient is human epidermal growth factor receptor 2 (HER2)-negative confirmed by an FDA-approved test
  - The requested agent will be used in combination with an aromatase inhibitor or fulvestrant
  - If the patient is male, patient will also receive concomitant suppression of testicular steroidogenesis

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Palbociclib (Ibrance)

References: N/A

Last review/revision date: 9/2022

Palovarotene (Sohonos)

Specific Therapeutic Class: *Retinoic Acid Receptor Gamma Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Heterotopic Ossification

Prescribing Restriction:

- Quantity Limit*:
  - 1mg: #56 per 28 days
  - 1.5mg:#84 per 28 days
  - 2.5mg: #84 per 28 days
  - 10mg: #56 per 28 days
- Prescriber restriction: Prescribed by or in conjunction with a physician that specializes in rare connective tissue disease

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Heterotopic ossification**, approve if:
  - If the patient is male, they are 10 years of age or older
  - If the patient is female, they are 8 years of age or older
  - Patient has a confirmed diagnosis of Fibrodysplasia Ossificans Progressiva
  - Patient has a ACVR1 R206H gene mutation confirmed by an FDA-approved genetic test

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is physician documentation that the patient continues to benefit from therapy confirmed by medical records

References: N/A

Last review/revision date: 9/2023

Panobinostat (Farydak)

Specific Therapeutic Class: *Antineoplastic Agent, Histone Deacetylase (HDAC) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Multiple myeloma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Multiple Myeloma,** approve if:
  - Patient is 18 years of age or older
  - The requested agent will be used in combination with bortezomib and dexamethasone
  - Patient has received at least 2 prior chemotherapy regimens including bortezomib and an immunomodulatory agent

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2022

Parathyroid Hormone (Natpara)

Specific Therapeutic Class: *Parathyroid Hormone Analog*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hypocalcemia Associated with Hypoparathyroidism

Prescribing Restriction:

- Quantity Limit*: #2 per 28 days
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hypocalcemia Associated with Hypoparathyroidism**, approve if:
  - The patient has ALL of the following:
    - The patient has baseline vitamin D levels above the lower limit of normal
    - The patient has baseline serum calcium levels above 7.5 mg/dL
    - The patient has had an inadequate response to maximally tolerated calcium AND vitamin D supplements (e.g., calcitriol, ergocalciferol, cholecalciferol)
    - The patient does NOT have hypoparathyroidism caused by calcium- sensing receptor mutations
    - The patient does NOT have acute post-surgical hypoparathyroidism
  - The patient is NOT at an increased risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing to osteosarcoma or patients with a history of prior external beam or implant radiation therapy involving the skeleton)
  - ONE of the following:
    - The patient is NOT currently being treated with alendronate
    - The patient is currently being treated with alendronate AND will discontinue prior to initiating the requested agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Parathyroid Hormone (Natpara)

Last review/revision date: 10/2023

Pasireotide (Signifor)

Specific Therapeutic Class: *Somatostatin Analog*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Cushing's Syndrome

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cushing's Syndrome**, approve if:
  - The requested agent will NOT be used for acromegaly
  - One of the following:
    - Documented inability for pituitary surgery
    - Patient has undergone pituitary surgery that was not curative
    - Patient has undergone pituitary surgery and has reoccurrence of symptoms
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least one of the following alternatives: cabergoline or temozolomide
  - The prescribed dose is within FDA approved recommendations

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose

References: N/A

Last review/revision date: 10/2023

Patiromer (Veltassa)

Specific Therapeutic Class: *Antidote; Potassium Binder*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hyperkalemia

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hyperkalemia**, approve if:
  - Patient has a diagnosis of hyperkalemia confirmed by an FDA-approved test
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sodium polystyrene sulfonate powder at up to maximally indicated doses
  - Patient is not taking another medication known to cause hyperkalemia (ACE inhibitor, ARB, aldosterone antagonist, etc)
  - Prescribed quantity is less than or equal to 25.2gm/day

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is currently receiving medication or has previously met initial approval criteria
- Patient still has hyperkalemia diagnosis
- Member is responding positively to therapy
- If request is for a dose increase, new dose does not exceed 25.2 gm/day

References: N/A

Last review/revision date: 3/2022

Pazopanib (Votrient)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Renal cell carcinoma
- Soft tissue sarcoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Renal Cell Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sunitinib
  - Patient does not have severe hepatic impairment (bilirubin >3x ULN, etc)

- For the diagnosis of **Soft Tissue Sarcoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease
  - Patient has received at least 1 previous chemotherapy treatment
  - Patient does not have severe hepatic impairment (bilirubin >3x ULN, etc)

- For the diagnosis of **Off-Label Indications**, approve if:

Pazopanib (Votrient)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2022

Peanut Powder (Palforzia)

Specific Therapeutic Class: *Allergen-Specific Immunotherapy*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Peanut Allergy

Prescribing Restriction:

- Quantity Limit*:
  - Initial dose escalation and up-dosing: Max of 14 capsules/14 days
  - Maintenance: #30 Packets per 30 days
- Prescriber restriction: Prescribed by or in consultation with an Allergist/Immunologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Peanut Allergy**, approve if:
  - Patient has a peanut allergy confirmed by one of the following:
    - Serum peanut specific IgE level of greater than or equal to 0.35 kUA/L
    - Positive skin prick test to peanut ≥ 3mm compared to control
  - One of the following:
    - Patient is between 4 and 17 years of age if in initiation phase
    - Patient is at least 4 years of age if in maintenance phase
  - Patient does not have Uncontrolled asthma
  - Patient does not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
  - Patient does not have a history of mast cell disorder, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema
  - Dose is appropriate for patients' stage in therapy

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose

References: N/A

Last review/revision date: 10/2023

Pegcetacoplan (Empaveli)

Specific Therapeutic Class: *Complement Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Paroxysmal Nocturnal Hemoglobinuria

Prescribing Restriction:

- Quantity Limit*: #8 per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Hematologist, Oncologist, or immunology specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Paroxysmal Nocturnal Hemoglobinuria**, approve if:
  - The patient has a diagnosis of PNH confirmed by flow cytometry
  - The patient is 18 years of age or older
  - The patient must have received ALL of the following vaccines at least 2 weeks prior to initiating therapy:
    - Haemophilus influenzae type b (Hib)
    - Meningococcal
    - Pneumococcal
  - One of the following:
    - Patient is transfusion-dependent (hemoglobin ≤7 g/dL OR hemoglobin ≤9 g/dL and is experiencing symptoms of anemia)
    - Patient has documented symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage)
  - The prescribed dose is less than or equal to 1080mg twice weekly via subcutaneous route

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable, continuing the medication, and tolerating therapy
- There is documentation of a positive response (any of the following):
  - Decrease in transfusions
  - Increase in hemoglobin levels
  - Normalization in LDH levels

References: N/A

Pegcetacoplan (Empaveli)

Last review/revision date: 10/2023

Pegfilgrastim (Neulasta)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
  - Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome,** approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose
  - There is documentation of trial and failure (i.e., failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged anti-infectives) with an adequate trial (including dates, doses of therapy) of at least 2 biosimilar agents OR there is a documented medical reason (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using a biosimilar agent

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose
  - There is documentation of trial and failure (i.e., failure to reach and/or maintain target ANC, prolonged febrile neutropenia, unplanned hospitalization, infection requiring prolonged anti-infectives) with an adequate trial (including dates, doses of therapy) of at least 2 biosimilar agents OR there is a documented medical reason (intolerance, hypersensitivity, dose dense chemotherapy, or stem cell collection, etc.) for not using a biosimilar agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

Pegfilgrastim (Neulasta)

- Patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2022

Pegfilgrastim-apgf (Nyvepria)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
  - Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2022

Pegfilgrastim-bmez (Ziextenzo)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
  - Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2022

Pegfilgrastim-cbqv (Udenyca)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
  - Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2022

Pegfilgrastim-fpgk (Stimufend)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
  - Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is still receiving chemotherapy

References: N/A

Last review/revision date: 12/2022

Pegfilgrastim-jmdb (Fulphila)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
  - Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2022

Pegfilgrastim-pbbk (Fylnetra)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Acute hematopoietic radiation injury syndrome
- Prevention of chemotherapy-induced neutropenia

Prescribing Restriction:

- Quantity Limit*: 0.6 ml per chemotherapy cycle, 1.2ml per 28 days
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome**, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Prevention/Treatment of Chemotherapy-Induced Neutropenia,** approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is still receiving chemotherapy

References: N/A

Last review/revision date: 10/2022

Peginterferon Alfa -2B (Sylatron)

Specific Therapeutic Class: *Antineoplastic Agent, Biological Response Modulator; Biological Response Modulator; Interferon*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Melanoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Melanoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has microscopic or gross nodal involvement
  - Patient is within 84 days of definitive surgical resection, including complete lymphadenectomy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2022

Peginterferon Alfa-2a (Pegasys, Pegasys Proclick)

Specific Therapeutic Class: *Interferon*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 48 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)
- Hepatitis B Viral Infection (HBV)

Prescribing Restriction:

- Quantity Limit*: #4 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 5 years of age or older
  - Patient has compensated liver disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glecaprevir/pibrentasvir (Mavyret)
  - The requested agent will be used in combination with ribavirin or there is documented intolerance or contraindication to use ribavirin

- For the diagnosis of **Hepatitis B Viral Infection (HBV)**, approve if:
  - Patient is 3 years of age or older
  - Patient has compensated liver disease
  - There is documentation of evidence of viral replication
  - Patient has liver inflammation confirmed by an FDA-approved test

References: N/A

Last review/revision date: 8/2022

Peginterferon Beta-1a (Plegridy)

Specific Therapeutic Class: *Biological Response Modulator; Interferon*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*: #2 per 28 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Pegvaliase-PGPZ (Palynziq)

Specific Therapeutic Class: *Phenylalanine Ammonia Lyase Enzyme; Phenylalanine Ammonia Lyase, Recombinant*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Phenylketonuria (PKU)

Prescribing Restriction:

- Quantity Limit*: #60ml per 30 days
- Prescriber restriction: Prescribed by or in consultation with an endocrinologist, metabolic disease specialist, or genetic disease specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Phenylketonuria (PKU)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of recent (within 90 days) phenylalanine (Phe) blood level is > 600 µmols/L
  - Palynziq is not prescribed concurrently with Sapropterin (Kuvan)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Sapropterin
  - The patient has also been prescribed auto-injectable epinephrine

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- One of the following:
  - Patient blood Phe level has decreased by ≥ 20% from pre-treatment baseline
  - Patient blood Phe level is ≤ 600 µmol/L

References: N/A

Last review/revision date: 10/2023

Pegvisomant (Somavert)

Specific Therapeutic Class: *Growth Hormone Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Acromegaly

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescriber is an Endocrinologist or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acromegaly**, approve if:
  - Patient's diagnosis is confirmed by one of the following:
    - Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
    - Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis
  - One of the following:
    - Patient has had an inadequate response to surgery or radiation
    - Surgery or radiation therapy are not appropriate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use injectable octreotide.

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- The patient's IGF-1 level has decreased or normalized from baseline

References: N/A

Last review/revision date: 4/2022

Pemigatinib (Pemazyre)

Specific Therapeutic Class: *Antineoplastic Agent, Fibroblast Growth Factor Receptor (FGFR) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cholangiocarcinoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cholangiocarcinoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has unresectable locally advanced or metastatic disease
  - Patient has a fibroblast growth factor receptor 2 fusion or other rearrangement confirmed by an FDA-approved test
  - Patient has had at least 1 prior chemotherapy regimen

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

Pemigatinib (Pemazyre)

References: N/A

Last review/revision date: 10/2023

Penicillamine (Cuprimine, Depen, D-Penamine)

Specific Therapeutic Class: Chelating Agent
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite

Diagnosis Considered for Coverage:

- Wilson's Disease
- Cystinuria

Prescribing Restriction:

- Quantity Limits*:
  - 125mg: 6 capsules/day (1500 mg/day divided)
  - 250mg: 6 capsules/day (1500 mg/day divided)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Wilson's Disease**, approve if:
  - Patient has a confirmed diagnosis of Wilson's disease

- For diagnosis of **Cystinuria**, approve if:
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use conservative measures (high fluid intake, sodium and protein restriction, urinary alkalinization, etc)

References: N/A

Last review/revision date: 2/2022

Pentosan Polysulfate Sodium (Elmiron)

Specific Therapeutic Class: *Analgesic, Urinary*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Interstitial cystitis

Prescribing Restriction:

- Quantity Limit*: #90 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Urologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Interstitial Cystitis**, approve if:
  - Diagnosis of bladder pain or discomfort associated with interstitial cystitis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use NSAIDs and tricyclic antidepressants

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has experienced improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)

References: N/A

Last review/revision date: 9/2022

Pexidartinib (Turalio)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Tenosynovial giant cell tumor
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Tenosynovial Giant Cell Tumor**, approve if:
  - Patient is 18 years of age or older
  - Patient and prescriber meet all REMS criteria
  - Disease is associated with severe morbidity or functional limitations
  - Patient has had prior surgical treatment or patient is not a candidate for surgery
  - If the patient is a female of reproductive potential, patient will be counseled to use effective contraception during treatment and for 1 week after the final dose
  - If the patient is a male with a female partner of reproductive potential, patient will be counseled to use effective contraception during treatment and for 1 week after the final dose

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Pexidartinib (Turalio)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2022

Phenoxybenzamine (Dibenzyline)

Specific Therapeutic Class: *Alpha1 Blocker; Antidote*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Pheochromocytoma

Prescribing Restriction:

- Quantity Limit*: 12 capsules per day
- Prescriber restriction: Prescribed by or in consultation with a Cardiologist or Endocrinologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pheochromocytoma**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following alternatives: doxazosin, prazosin, or terazosin

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose

References: N/A

Last review/revision date: 4/2022

Pimavanserin (Nuplazid)

Specific Therapeutic Class: *Second Generation (Atypical) Antipsychotic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Parkinson disease psychosis

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Parkinson Disease Psychosis**, approve if:
  - Patient is 18 years of age or older
  - There is documentation submitted of medical records documenting the presence of hallucinations or delusions (which may include illusions or a false sense of presence) on a recurrent or continuous basis for at least 1 month
  - There is documentation submitted of medical records documenting the prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting Nuplazid
  - The requested agent will be used in combination with other Parkinson's disease medication(s)

References: N/A

Last review/revision date: 1/2023

Pirfenidone (Esbriet)

Specific Therapeutic Class: *Anti-inflammatory Agent; Antifibrotic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Idiopathic pulmonary fibrosis

Prescribing Restriction:

- Quantity Limit*:
  - 267mg tablet/capsule: #180/30 days
  - 801mg tablet: #90/30 days
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Idiopathic pulmonary fibrosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of Idiopathic pulmonary fibrosis confirmed by all of the following:
    - Physical exam
    - FVC<82% of predicted
    - TLC<80% of predicted
    - CT with classic findings of usual interstitial pneumonitis (UIP)
  - There are no known causes of the patients interstitial lung disease

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of patient improvement based on a slowed the rate of decline of lung function, improved (or no decline in) symptoms of cough or shortness of breath or improved sense of well-being

References: N/A

Last review/revision date: 9/2022

Pirtobrutinib (Jayprica)

Specific Therapeutic Class: *Antineoplastic Agent, Bruton Tyrosine Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Chronic lymphocytic leukemia/small lymphocytic lymphoma, relapsed or refractory
- Mantle cell lymphoma (relapsed/refractory)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **chronic lymphocytic leukemia/small lymphocytic lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has relapsed or refractory disease
  - There is documentation of trial and failure of at least two prior lines of systemic therapy, including a Bruton Tyrosine Kinase (BTK) inhibitor and a B-cell leukemia/lymphoma-2 (BCL-2) inhibitor

- For the diagnosis of **mantle cell lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has relapsed or refractory disease
  - There is documentation of trial and failure of at least two prior lines of systemic therapy, including a Bruton Tyrosine Kinase (BTK) inhibitor

- For the diagnosis of **Off-Label Indications**, approve if:

Pirtobrutinib (Jayprica)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 2/2024

Pitolisant (Wakix)

Specific Therapeutic Class: *Central Nervous System Stimulant; Histamine-3 (H3) Receptor Antagonist/Inverse Agonist*
Formulary Status: Non-formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Narcolepsy with excessive daytime sleepiness,
- Narcolepsy with cataplexy

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist or sleep specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Narcolepsy with Excessive Daytime Sleepiness**, approve if:
  - Patient is ≥ 18 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two stimulants

- For the diagnosis of **Narcolepsy with Cataplexy**, approve if:
  - Patient is ≥ 18 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy
  - If the patient has a history of substance abuse, documentation has been provided that the prescriber has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use as least two stimulants
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following: SSRI, TCA, or venlafaxine

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

Pitolisant (Wakix)

- Patient is stable and continuing the medication
- Documentation has been submitted indicating patient has clinically benefited from treatment (i.e., improvement on Epworth Sleepiness score or other documentation)
- For cataplexy, documentation has been provided that there has been a reduction in frequency of cataplexy attacks

References: N/A

Last review/revision date: 10/2023

Plerixafor (Mozobil)

Specific Therapeutic Class: *Hematopoietic Agent; Hematopoietic Stem Cell Mobilizer*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 4 days
- Continuation: N/A

Diagnosis Considered for Coverage:

- Mobilization of hematopoietic stem cells for collection and subsequent autologous transplantation (in combination with filgrastim) in patients with non-Hodgkin lymphoma and multiple myeloma

Prescribing Restriction:

- Quantity Limit*: #8 vials (9.6ml) per 4 days
- Prescriber restriction: Prescriber is a bone marrow transplant specialist, Hematologist, or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hematopoietic Stem Cell Mobilization**, approve if:
  - Patient is at least 18 years of age
  - Patient had been diagnosed with non-Hodgkin's lymphoma (NHL) or multiple myeloma and the diagnosis has been confirmed by an FDA-approved test
  - Patient is scheduled for autologous transplantation
  - The requested agent will be used in combination with filgrastim or its biosimilars

References: N/A

Last review/revision date: 9/2022

Pomalidomide (Pomalyst)

Specific Therapeutic Class: *Angiogenesis Inhibitor; Antineoplastic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Kaposi sarcoma
- Multiple myeloma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Kaposi Sarcoma,** approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Patient is HIV negative confirmed by an FDA-approved test
    - Patient is HIV positive and has failed highly active antiretroviral therapy (HAART)

- For the diagnosis of **Multiple Myeloma,** approve if:
  - Patient is 18 years of age or older
  - The requested agent will be used in combination with dexamethasone
  - Patient has received at least 2 prior chemotherapy regimens including lenalidomide and a proteasome inhibitor
  - Patient has demonstrated progression on or within 60 days of completion of the last therapy

- For the diagnosis of **Off-Label Indications**, approve if:

Pomalidomide (Pomalyst)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Ponatinib (Iclusig)

Specific Therapeutic Class: *Antineoplastic Agent, BCR-ABL Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute lymphoblastic leukemia
- Chronic myeloid leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Lymphoblastic Leukemia**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Both of the following
      a. Patient is Philadelphia chromosome-positive (Ph+) confirmed by an FDA-approved test
      b. Patient has no other kinase inhibitors indicated
    - Patient has T315I-positive Ph+ disease confirmed by an FDA-approved test

- For the diagnosis of **Chronic Myeloid Leukemia**, approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Both of the following
      a. Patient is in chronic phase
      b. Patient has resistance or intolerance to at least 2 prior kinase inhibitors
    - Both of the following

Ponatinib (Iclusig)

a. Patient is in accelerated or blast phase
b. Patient has no other kinase inhibitors indicated

- Both of the following
  a. Patient is in chronic, accelerated, or blast phase
  b. Patient is T315I-positive confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Ponesimod (Ponvory)

Specific Therapeutic Class: Sphingosine 1-Phosphate (S1P) Receptor Modulator
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
  - Will not be used in combination with any other disease-modifying MS agent
  - The patient does not have a history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
  - The patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: interferon beta-1a (Rebif, Avonex), fingolimod (Gilenya), cladribine (Mavenclad), peginterferon beta-1a (Plegridy), teriflunomide (Aubagio), Siponimod (Mayzent), or diroximel fumarate (Vumerity)
  - Will not be used in combination with any other disease-modifying MS agent

Ponesimod (Ponvory)

- The patient does not have a history (within the last 6 months) of myocardial infarction, unstable
- angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- The patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Posaconazole (Noxafil)

Specific Therapeutic Class: *Antifungal Agent, Azole Derivative*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Aspergillosis
- Oropharyngeal Candidiasis
- Prophylaxis against invasive fungal infections

Prescribing Restriction:

- Quantity Limit*:
- Tablets: #91 per 30 days
- Suspension: 600ml per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Aspergillosis**, approve if:
  - Patient is 13 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **voriconazole AND itraconazole**
  - If the prescription is written for Noxafil 300mg packs, there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic posaconazole tablets

- For the diagnosis of **Oropharyngeal Candidiasis**, approve if:
  - Patient is 13 years of age or older
  -
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **fluconazole**
  - If the prescription is written for Noxafil 300mg packs, there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic posaconazole tablets

- For the diagnosis of **Prophylaxis Against Invasive Fungal Infections**, approve if:

Posaconazole (Noxafil)

- Patient is 2 years of age or older
- Patient is severely immunocompromised (eg, hematopoietic stem cell transplant with graft-versus-host disease, hematologic malignancy with prolonged neutropenia due to chemotherapy)
- If the prescription is written for Noxafil 300mg packs, there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic posaconazole tablets

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Documented response to therapy
- Additional therapy is medically necessary and clinically appropriate

References: N/A

Last review/revision date: 10/2023

Pralsetinib (Gavreto)

Specific Therapeutic Class: *Antineoplastic Agent, RET Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer
- Thyroid cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient is RET fusion-positive confirmed by an FDA-approved test

- For the diagnosis of **Thyroid Cancer**, approve if:
  - Patient is 12 years of age or older
  - One of the following:
    - All of the following
      a. Patient has medullary disease
      b. Patient has advanced or metastatic disease
      c. Patient has a RET-positive mutation confirmed by an FDA approved test
      d. Patient requires systemic therapy
    - All of the following
      a. Patient is RET fusion-positive confirmed by an FDA-approved test

Pralsetinib (Gavreto)

b. Patient requires systemic therapy
c. Patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Prednisone DR (Rayos)

Specific Therapeutic Class: *Corticosteroid, Systemic*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: N/A

Diagnosis Considered for Coverage:

- Inflammatory conditions such as COPD, Rheumatoid arthritis, etc

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For **Inflammatory Conditions**, approve if:
  - The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to generic oral prednisone AND at least 1 other different generic oral corticosteroid (e.g., dexamethasone, methylprednisolone, prednisolone) that would not be expected to occur with the requested agent
  - The prescriber has submitted documentation regarding the medical necessity of the requested agent over generic prednisone
  - ONE of the following:
    - The requested quantity (dose) does not exceed the program quantity limit
    - ALL of the following
      a. The requested quantity (dose) is greater than the quantity limit
      b. The requested quantity (dose) does not exceed the maximum FDA labeled dose
      c. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    - ALL of the following:
      a. The requested quantity (dose) is greater than the program quantity limit
      b. The requested quantity (dose) is greater than the maximum FDA labeled dose
      c. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

References: N/A

Last review/revision date: 1/2023

Procarbazine (Matulane)

Specific Therapeutic Class: *Antineoplastic Agent, Alkylating Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hodgkin's lymphoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hodgkin's Lymphoma,** approve if:
  - Patient has stage III or IV disease
  - The requested agent will be used in combination with other chemotherapy agents

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2022

Propranolol (Hemangeol)

Specific Therapeutic Class: *Antianginal Agent; Antiarrhythmic Agent, Class II; Antihypertensive; Beta-Adrenergic Blocker, Nonselective*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Proliferating infantile hemangioma

Prescribing Restriction:

- Quantity Limit*: #360ml per 30 days
- Prescriber restriction: Prescribed by or in consultation with a pediatric dermatologist or provider with experience treating hemangiomas

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **proliferating infantile hemangioma**, approve if:
     - Patient is 5 weeks of age or older
     - Patient weighs greater than or equal to 2kg
     - Patient has a documented diagnosis of proliferating infantile hemangioma that requires systemic therapy
     - Patient does not have a sustained heart rate less than 80 beats per minute, greater than first degree heart block, sustained blood pressure less than 50/30 mmHg, or decompensated heart failure

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - Patient has shown clinical improvement while on therapy
   - Patient has recurrence of hemangiomas

References: N/A

Last review/revision date: 2/2024

Pyrimethamine (Daraprim)

Specific Therapeutic Class: *Antimalarial Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Toxoplasmosis

Prescribing Restriction:

- Quantity Limit*: #90 per 30 days
- Prescriber restriction: HIV specialist, Infectious Disease specialist, Internal Medicine specialist, or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Toxoplasmosis,** approve if:
  - If the request is for treatment of Toxoplasmosis, all of the following:
    - Diagnosis of Toxoplasmosis confirmed by an FDA-approved test
    - Documented immunosuppression (i.e., CD4+ count ≤ 200/mm3)
    - Requested agent will be used in combination with sulfonamide and folinic acid
  - If the request is for prophylaxis of Toxoplasmosis, all of the following:
    - Requested agent will be used in combination with ONE of the following:
      a. Dapsone + leucovorin
      b. Atovaquone + leucovorin
    - Patient is also receiving anti-retroviral therapy (ART)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfamethoxazole/trimethoprim
    - Patient has a CD4+ count ≤ 100/mm3

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Medical justification provided for continuation of therapy

References: N/A

Last review/revision date: 10/2023

Quantity Limit Exception

Formulary Status: Formulary, PA or Non-formulary

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA approved indications
- See off-label criteria

Prescribing Restriction:

- Quantity Limit: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- Approve if:
  - One of the following:
    - The patient has documented treatment failure despite compliance while taking the drug prescribed at the quantity limit
    - The patient requires a weight-based dose above the quantity limit and that is less than or equal to the FDA-approved maximum dose
    - Medical justification is provided as to why the plan's quantity limit will be inadequate based on the patient's condition and treatment history confirmed by medical records
  - One of the following:
    - A higher strength dosage form with a prescribed quantity within acceptable quantity limits will not adequately treat the patients condition
    - A higher strength dosage form with a prescribed quantity within acceptable quantity limits does not reasonably correspond with the patients prescribed dose or dosing frequency
    - A higher strength dosage form with a prescribed quantity within acceptable quantity limits is unavailable
  - The requested dose is supported by Medical Compendia, current treatment guidelines, or literature with a reasonable level of evidence (ex: no case reports, retrospective studies, or small single-center studies)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 7/2023

Quizartinib (Vanflyta)

Specific Therapeutic Class: *Antineoplastic Agent, FLT3 Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute Myeloid Leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Quantity Limit: Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia**, approve if:
  - Patient is 18 years of age or older
  - Patient is FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)–positive confirmed by an FDA-approved test
  - One of the following:
    - The requested agent will be used in combination with cytarabine and anthracycline induction therapy
    - The requested agent will be used in combination with cytarabine consolidation therapy
    - The requested agent will be used as monotherapy following induction therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert

Quizartinib (Vanflyta)

- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 8/2023

Regorafenib (Stivarga)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Colorectal cancer
- GI stromal tumors
- Hepatocellular carcinoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Colorectal Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF therapy
  - If the patient is RAS wild type, patient has been previously treated with an anti-EGFR therapy

- For the diagnosis of **GI Stromal Tumors**, approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced, unresectable, or metastatic disease
  - Patient has been previously treated with imatinib and sunitinib

- For the diagnosis of **Hepatocellular Carcinoma,** approve if:

Regorafenib (Stivarga)

- Patient is 18 years of age or older
- Patient has been previously treated with sorafenib

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2022

Relugolix (Orgovyx)

Specific Therapeutic Class: *Antineoplastic Agent, Gonadotropin-Releasing Hormone Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Prostate cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prostate Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Relugolix-Estradiol-Norethindrone (Myfembree)

Therapeutic Category: *Estrogen Derivative; Gonadotropin Releasing Hormone Agonist; Progestin*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
- Moderate to severe pain associated with endometriosis

Prescribing Restrictions:

- Quantity Limit: #28 per 28 days

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy
- Current therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Heavy Menstrual Bleeding associated with Uterine Leiomyomas (Fibroids),** approve if:
  - Patient is 18 years of age or older
  - Patient is premenopausal
  - If the fibroids are submucosal only, there is documentation submitted for failure or inability to undergo hysteroscopic resection of submucosal fibroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use **at least 2** of the following:
    - Estrogen-progestin contraceptives
    - Progestin-only contraceptives
    - Progestin-releasing intrauterine device (IUD)
    - Oral Tranexamic acid
  - Patient is NOT at high risk of arterial, venous thrombotic, or thromboembolic disorders defined by ONE of the following:
    - Patient is >35 years of age and both of the following
      - Is a current smoker
      - Headaches with focal neurological symptoms or have migraine headaches with aura
    - Patient has a current or history of deep vein thrombosis or pulmonary embolism
    - Patient has known vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)

Relugolix-Estradiol-Norethindrone (Myfembree)

        - Patient has thrombogenic valvular or thrombogenic rhythm diseases of the heart (ex. subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
        - Patient has inherited or acquired hypercoagulopathies
        - Patient has uncontrolled hypertension
        - Patient does not have headaches with focal neurological symptoms or migraine headaches with aura if >35 years of age
    - Patient is not pregnant or planning to become pregnant
    - Patient does not have osteoporosis
    - No current or history of breast cancer or other hormonally sensitive malignancies or increased risk for hormonally sensitive malignancies
    - No hepatic impairment or disease
    - Does not have undiagnosed abnormal uterine bleeding
    - The prescribed dose is 1 tablet per day

- For the diagnosis of **Endometrosis** approve if:
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use two generic analgesics (ibuprofen, meloxicam, naproxen, etc.)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use combined oral contraceptive or progestin
    - Patient is 18 years of age or older
    - Patient is premenopausal
    - Patient is NOT at high risk of arterial, venous thrombotic, or thromboembolic disorders defined by ONE of the following:
        - Patient is >35 years of age and both of the following
            - Is a current smoker
            - Headaches with focal neurological symptoms or have migraine headaches with aura
        - Patient has a current or history of deep vein thrombosis or pulmonary embolism
        - Patient has known vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
        - Patient has thrombogenic valvular or thrombogenic rhythm diseases of the heart (ex. subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
        - Patient has inherited or acquired hypercoagulopathies
        - Patient has uncontrolled hypertension
        - Patient does not have headaches with focal neurological symptoms or migraine headaches with aura if >35 years of age
    - Patient is not pregnant or planning to become pregnant
    - Patient does not have osteoporosis

Relugolix-Estradiol-Norethindrone (Myfembree)

- No current or history of breast cancer or other hormonally sensitive malignancies or increased risk for hormonally sensitive malignancies
- No hepatic impairment or disease
- Does not have undiagnosed abnormal uterine bleeding
- The prescribed dose is 1 tablet per day

III. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose
- Total treatment duration is less than 24 months

References: N/A

Last review/revision date: 1/2023

Repotrectinib (Augtyro)

Specific Therapeutic Class: *Antineoplastic Agent, Proto-Oncogene Tyrosine-Protein Kinase Inhibitor, Tropomyosin Receptor Kinase (TRK) Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer, locally advanced or metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-small cell lung cancer,** approve if:
  - Patient has a diagnosis of Non-small cell lung cancer confirmed by an FDA-approved test
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient is *ROS1*-positive confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Repotrectinib (Augtyro)

Last review/revision date: 1/2024

Resmetirom (Rezdiffra)

Specific Therapeutic Class: *Thyroid Hormone Receptor-Beta Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Noncirrhotic nonalcoholic steatohepatitis (NASH)

Prescribing Restriction:

- Quantity Limit: #30 tablets per 30 days
- Prescriber restriction: Gastroenterologists or Hepatologists

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Actual patient weight
- Medication history

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Noncirrhotic nonalcoholic steatohepatitis (NASH)**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of NASH with moderate to advanced liver fibrosis confirmed by biopsy *or* NITs
  - If the patient has a BMI greater than or equal to 27, there is documented trial and failure (less than 5% loss in total body weight) with documented compliance to at least 6 months of lifestyle modifications including diet (~500kcal daily deficit) and exercise (at least 150 minutes per week)
  - Patient does not have a history of excessive alcohol use (alcohol consumption of more than 20 g per day for women and more than 30 g per day for men) in the past year

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in laboratory tests and other NITs

References: N/A

Last review/revision date: 6/2024

Ribociclib (Kisqali)

Specific Therapeutic Class: *Antineoplastic Agent, Cyclin-Dependent Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced or metastatic disease
  - Patient is hormone receptor (HR)-positive confirmed by an FDA-approved test
  - Patient is human epidermal growth factor receptor 2 (HER2)-negative confirmed by an FDA-approved test
  - One of the following:
    - Both of the following:
      a. The requested agent will be used as initial endocrine-based therapy
      b. Requested agent will be used in combination with an aromatase inhibitor
    - Both of the following:
      a. Patient is postmenopausal
      b. Requested agent will be used in combination with fulvestrant

- For the diagnosis of **Off-Label Indications**, approve if:

Ribociclib (Kisqali)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2022

Ribociclib-Letrozole (Kisqali Femara)

Specific Therapeutic Class: *Antineoplastic Agent, Aromatase Inhibitor, Cyclin-Dependent Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast Cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced or metastatic disease
  - Patient is hormone receptor (HR)-positive confirmed by an FDA-approved test
  - Patient is human epidermal growth factor receptor 2 (HER2)-negative confirmed by an FDA-approved test
  - Requested agent will be used as initial endocrine-based therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Ribociclib-Letrozole (Kisqali Femara)

Last review/revision date: 9/2022

Rilonacept (Arcalyst)

Specific Therapeutic Class: *Interleukin-1 Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Cryopyrin-associated periodic syndromes
- Deficiency of interleukin-1 receptor antagonist
- Pericarditis, recurrent

Prescribing Restriction:

- Quantity Limit*: #8 per 28 days
- Prescriber restriction: See individual indications below

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cryopyrin-Associated Periodic Syndromes**, approve if:
  - Patient is 12 years of age or older
  - The prescriber is a specialist in the area of the patient's requested indication or has consulted with a specialist in the area of the patient's requested indication (e.g., allergist, autoimmune specialist, immunologist, pediatrician)
  - ONE of the following:
    - The patient is NOT currently being treated with another biologic immunomodulator
    - The patient is currently being treated with another biologic immunomodulator and it will be discontinued prior to starting the requested agent
  - The patient does NOT have any FDA labeled contraindication(s) to the requested agent

- For the diagnosis of **Deficiency of Interleukin-1 Receptor Antagonist**, approve if:
  - Patient weighs 10kg or more
  - The prescriber is a specialist in the area of the patient's requested indication or has consulted with a specialist in the area of the patient's requested indication (e.g., allergist, autoimmune specialist, immunologist, pediatrician)
  - ONE of the following:
    - The patient is NOT currently being treated with another biologic immunomodulator
    - The patient is currently being treated with another biologic immunomodulator and it will be discontinued prior to starting the requested agent

Rilonacept (Arcalyst)

- The patient does NOT have any FDA labeled contraindication(s) to the requested agent

- For the diagnosis of **Recurrent Pericarditis**, approve if:
  - Patient is 12 years of age or older
  - The prescriber is a specialist in the area of the patient's requested indication or has consulted with a specialist in the area of the patient's requested indication (e.g., allergist, autoimmune specialist, immunologist, pediatrician)
  - ONE of the following:
    - The patient is NOT currently being treated with another biologic immunomodulator
    - The patient is currently being treated with another biologic immunomodulator and it will be discontinued prior to starting the requested agent
  - The patient does NOT have any FDA labeled contraindication(s) to the requested agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ALL of the following:
    - NSAIDs
    - Corticosteroids
    - Colchicine

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- The patient has been previously approved for the requested agent through Prior Authorization process
- The patient has shown clinical improvement with the requested agent (i.e., improvement in serum levels of C-Reactive Protein (CRP), improvement in Serum Amyloid A (SAA), slowing of disease progression, decrease in symptom severity and/or frequency)

References: N/A

Last review/revision date: 5/2022

Riluzole (Tiglutik, Exservan)

Specific Therapeutic Class: *Glutamate Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Amyotrophic lateral sclerosis (ALS)

Prescribing Restriction:

- Quantity Limit*:
  - Tiglutik: 600ml per 30 days
  - Exservan: #60 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Amyotrophic Lateral Sclerosis (ALS)**, approve if:
  - The patient has a diagnosis of ALS confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use riluzole oral tablets (ex: inability to swallow tablets)
  - If the prescription is written for the riluzole oral suspension (Tiglutik), there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use the riluzole oral film (Exservan)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 10/2023

Rimegepant (Nurtec)

Standard/Specific Therapeutic Class: *Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist*
Formulary Status: Formulary

Coverage Duration:

- Initial: 12 months
- Re-authorization: 12 months

Diagnosis Considered for Coverage:

- Migraine
- Other diagnoses: see off-label criteria

Prescribing Restriction:

- Quantity Limit*: #8 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information required for Review:

- Diagnosis
- Previous and current therapy
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Migraine** approve if:
  - One of the following:
    - Prescribed quantity is less than or equal to #8 per 30 day
    - For requests over #8 per 30 days, there is there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to us at least 2 injectable CGRPs

III. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 5/2022

Riociguat (Adempas)

Specific Therapeutic Class: *Soluble Guanylate Cyclase Stimulator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary Arterial Hypertension (PAH)
- Chronic thromboembolic pulmonary hypertension (CTEPH)

Prescribing Restriction:

- Quantity Limit*: #90 tablets per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Current and previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pulmonary Arterial Hypertension (PAH)**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of PAH confirmed by RHC
  - There is documentation that the patient has WHO functional class (FC) II or III symptoms
  - The patient does not have idiopathic interstitial pneumonias (IPP)

- For the diagnosis of **WHO Group 4 Pulmonary Hypertension, or Chronic Thromboembolic Pulmonary Hypertension (CTEPH),** approve if:
  - Confirmed diagnosis and documentation of functional class (II-IV) by a cardiologist or pulmonologist
  - One of the following:
    - Patient has recurrent or persistent CTEPH following pulmonary thromboendarterectomy
    - Patient has inoperable CTEPH
  - The patient does not have idiopathic interstitial pneumonias (IPP)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Last review/revision date: 6/2024

Ripretinib (Qinlock)

Specific Therapeutic Class: *Antineoplastic Agent, KIT Inhibitor, PDGFR-alpha Blocker, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Gastrointestinal stromal tumor
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Gastrointestinal Stromal Tumors**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease
  - Patient has received prior treatment with 3 or more kinase inhibitors, including imatinib and sunitinib
  - If the patient is a female of reproductive potential, patient has been counseled to use effective contraception during treatment and for 1 week after the final dose
  - If the patient is a male with a female partner of reproductive potential, patient has been counseled to us effective contraception during treatment and for 1 week after the final dose

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert

Ripretinib (Qinlock)

- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 9/2022

Risankizumab-Rzaa (Skyrizi)

Therapeutic Category: *Antipsoriatic Agent; Interleukin-23 Inhibitor; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Plaque Psoriasis
- Psoriatic Arthritis
- Crohn's Disease

Prescribing Restrictions:

- Quantity Limit:
  - Plaque Psoriasis and Psoriatic Arthritis
    - Initial: 150mg at Week 0 and Week 4
    - Maintenance: 150mg every 12 weeks
  - Crohn's Disease
    - Maintenance only: 360mg Q8 weeks
- Prescriber restriction: Dermatologist, Rheumatologist, or Gastroenterologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)

Risankizumab-Rzaa (Skyrizi)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids

- For diagnosis of **Crohn's Disease**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of moderate to severely active Crohn's Disease
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Gastroenterologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use more conventional therapies for Crohn's Disease such as corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine.

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- Patient has not experienced drug-induced hepatotoxicity

References: N/A

Last review/revision date: 2/2024

Risdiplam (Evrysdi)

Specific Therapeutic Class: *Survival of Motor Neuron 2 (SMN2)-Directed RNA Splicing Modifier*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Spinal muscle atrophy

Prescribing Restriction:

- Quantity Limit*:
  - Initial fill: #160 ml per 24 days
  - All subsequent fills: #240 ml per 36 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
- For the diagnosis of **Spinal Muscle Atrophy**, approve if:
  - Patient is 2 months of age or older
  - Patient has a diagnosis of spinal muscle atrophy confirmed by an FDA-approve genetic test

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Dose is appropriate

References: N/A

Last review/revision date: 9/2022

Romiplostim (Nplate)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent; Thrombopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hematopoietic syndrome of acute radiation syndrome
- Immune thrombocytopenia

Prescribing Restriction:

- Quantity Limit*: A sufficient quantity for a 30 day supply of doses up to 10mcg/kg/ week
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hematopoietic Syndrome of Acute Radiation Syndrome**, approve if:
  - Patient has experienced acute exposure to Hematopoietic syndrome of acute radiation syndrome myelosuppressive radiation doses

- For the diagnosis of **Immune Thrombocytopenia**, approve if:
  - Patient is 1 year of age or older
  - If patient is less than 18 years of age, patient has had ITP for at least 6 months
  - Platelet level < 50,000 mm^3
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ONE of the following: glucocorticoids, intravenous immune globulin (IVIG), rituximab (Rituxan) if appropriate) or splenectomy

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2021

Romosozumab (Evenity)

Standard/Specific Therapeutic Class: *Monoclonal Antibody; Sclerostin Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration: 12 months

Diagnosis Considered for Coverage:

- Osteoporosis in postmenopausal females at high risk for fractures
- Patients who have failed or are intolerant to other osteoporosis therapies

Prescribing Restriction

- Quantity Limit*:
  - Evenity: #2.34ml (as #2 1.17ml Syringes) per 30 days (1 months)

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Dose
- T-score
- Fracture history

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Osteoporosis**, approve if:
  - One of the following:
    - Patient is a postmenopausal female at high risk for fractures (defined as a history of osteoporotic fracture or multiple risk factors for fracture)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use **bisphosphonates** and **denosumab (Prolia)**
  - Patient has a T-score < 2.5 OR T-score -1.0 and -2.5 with high risk of fracture or history of fracture
  - The patient does not have hypocalcemia OR hypocalcemia will be corrected prior to initiating therapy
  - The patient has not had a stroke or myocardial infarction in the past year

References: N/A

Last review/revision date: 10/2023

Ropeginterferon Alfa-2b (Besremi)

Specific Therapeutic Class: *Biological Response Modulator; Interferon*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Polycythemia vera

Prescribing Restriction:

- Quantity Limit*: 2ml per 28 days
- Prescriber restriction: Hematologist or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Polycythemia Vera**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of polycythemia vera confirmed by an FDA-approved test
  - Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of ≤2
  - Patient does not have moderate (Child-Pugh class B) or severe (Child-Pugh class C) hepatic impairment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use hydroxyurea

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation to support the need for continued therapy

References: N/A

Last review/revision date: 10/2022

Rucaparib (Rubraca)

Specific Therapeutic Class: *Antineoplastic Agent, PARP Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Ovarian cancer
- Prostate cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Ovarian Cancer,** approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - All of the following:
      a. Patient has advanced disease
      b. Patient is BRCA-positive confirmed by an FDA-approved test
      c. Patient has been previously treated with at least 2 prior chemotherapy regimens
    - All of the following:
      a. Patient has recurrent disease
      b. Patient has had a complete or partial response to platinum-based chemotherapy
      c. The requested agent will be used as maintenance treatment
  - If the patient is a female of reproductive potential, patient has been counseled to use effective contraception during therapy and for 6 months after the last dose
  - If the patient is a male with a female partner of reproductive potential, patient has been counseled to use effective contraception during therapy and for 3 months after the last dose

Rucaparib (Rubraca)

- For the diagnosis of **Prostate Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient metastatic disease
  - Disease is castration-resistant
  - Patient has a BRCA-positive mutation confirmed by an FDA-approved test
  - Patient has received previous treatment with at least two prior chemotherapy regimens including an androgen receptor-directed therapy and a taxane-based chemotherapy
  - Patient has had a bilateral orchiectomy OR patient will be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently with the requested agent
  - If the patient is a female of reproductive potential, patient has been counseled to use effective contraception during therapy and for 6 months after the last dose
  - If the patient is a male with a female partner of reproductive potential, patient has been counseled to use effective contraception during therapy and for 3 months after the last dose

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2022

Ruxolitinib (Jakafi)

Specific Therapeutic Class: *Antineoplastic Agent, Janus Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Myelofibrosis
- Polycythemia vera
- Graft-versus-host disease
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist, Hematologist, or transplant specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Myelofibrosis,** approve if:
  - Patient is 18 years of age or older
  - Patient has one of the following
    - Intermediate or high-risk disease
    - Primary myelofibrosis
    - Post-polycythemia vera myelofibrosis
    - Post-essential thrombocythemia myelofibrosis

- For the diagnosis of **Polycythemia Vera**, approve if:
  - Patient is 18 years of age or older
  - Patient has documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use hydroxyurea

- For the diagnosis of **Graft-Versus-Host Disease**, approve if:

Ruxolitinib (Jakafi)

- Patient is 12 years of age or older
- Patient has acute graft-versus-host disease
- Patient is steroid refractory

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2022

Ruxolitinib (Opzelura)

Specific Therapeutic Class: *Janus Kinase Inhibitor; Topical Skin Product*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: N/A

Diagnosis Considered for Coverage:

- Atopic dermatitis (mild to moderate)
- Nonsegmental vitiligo

Prescribing Restriction:

- Quantity Limit*: #4 tubes per 28 days
- Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Atopic Dermatitis**, approve if:
  - Patient is 12 years of age or older
  - Body surface area (BSA) involvement is greater than 10%
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 medium to high potency topical corticosteroid AND topical calcineurin inhibitor
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use crisaborole (Eucrisa)

- For the diagnosis of **Nonsegmental Vitiligo**, approve if:
  - Patient is 12 years of age or older
  - Facial body surface area (BSA) involvement is greater than or equal to 0.5%
  - Body surface area (BSA) involvement is greater than or equal to 3%
  - Total body surface area (BSA) involvement is less than or equal to 10%
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 2 of the following: 1 medium to high potency topical corticosteroid, topical calcineurin inhibitor, or targeted phototherapy

References: N/A

Last review/revision date: 11/2022

Sacrosidase (Sucraid)

Specific Therapeutic Class: *Enzyme, Gastrointestinal*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Congenital sucrase-isomaltase deficiency

Prescribing Restriction:

- Quantity Limit*: #240ml per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Gastroenterologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Congenital Sucrase-Isomaltase Deficiency**, approve if:
  - Patient is 5 months of age or older
  - Patient has a diagnosis of congenital sucrose-isomaltase deficiency confirmed by one of the following:
    - Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides
    - All of the following criteria:
      a. Stool pH <6
      b. Increase in breath hydrogen of >10ppm when challenged with sucrose after fasting
      c. Negative lactose breath test

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2022

Safety Edit Exception

Formulary Status: Formulary, PA or Non-formulary
**For drugs without specific criteria*

Coverage Duration: 1 year*
**One month approval for duplication of therapy when transitioning from one agent to another.*

Diagnosis Considered for Coverage:

- FDA approved indications
- See off-label criteria

Prescribing Restriction:

- Quantity Limit: N/A

Clinical Information Required for Review:

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose and duration of therapy
- Supporting documentation

Coverage Criteria:

I. Initiation of Therapy:

- **For requests exceeding the FDA or compendia max dose, administration frequency or duration of therapy recommendations, approve if:**
  - Patient has documented treatment failure with the drug at the maximum tolerated dose or maximum dose (whichever is the lesser dose), administration frequency, or duration of therapy
  - Medical justification why the maximum dose, administration frequency, or duration of therapy needs to be exceeded based on the member's condition or treatment history
  - Patient has tried other therapeutic options which have also failed or are inappropriate
  - Dose requested is supported by the Medical Compendia or current treatment guidelines

- **For requests for a duplication of therapy**
  - **Transition from one agent to another (**one month only**), approve if:**
    - Provider has outlined a plan to transition member to a similar drug
    - Provider has provided a dose titration schedule
  - **Ongoing concurrent therapy with two similar agents, approve if:**
    - Medical justification why treatment with more than one drug in the same class is required based on the patient's condition and treatment history
    - Provider has submitted disease state specific standard of care guidelines supporting concurrent therapy

- **For requests exceeding an age restriction, approve if:**
  - Medical justification why the drug is needed outside age limit

Safety Edit Exception

- Indication and dose requested are supported by the Medical Compendia or current treatment guidelines

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Medical justification for continuation of therapy

References: N/A

Last review/revision date: 12/2022

Safinamide (Xadago)

Specific Therapeutic Class: *Anti-Parkinson Agent, MAO Type B Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Adjunctive Treatment to Levodopa/Carbidopa in Patients with Parkinson's Disease (PD) Experiencing "Off" Episodes

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescriber is a Neurologist, or the prescriber has consulted with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Parkinson's Disease**, approve if:
  - Patient is 18 years of age or older
  - Patient is experiencing "off" time on levodopa/carbidopa therapy
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Rasagiline (Azilect) AND one of the following:
    - Entacapone (Comtan/Stalevo),
    - Ropinirole/ropinirole ER (Requip/Requip XL)
    - Pramipexole/pramipexole ER (Mirapex/Mirapex ER)
    - Neupro (ritigotine)
  - The requested agent is prescribed in combination with carbidopa/levodopa
  - Prescribed dose does not exceed 100 mg once daily

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Prescribed dose does not exceed 100 mg once daily

References: N/A

Last review/revision date: 1/2023

Sapropterin (Javygtor, Kuvan)

Specific Therapeutic Class: *Endocrine and Metabolic Agents-Miscellaneous*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Phenylketonuria (PKU) with hyperphenylalaninemia

Prescribing Restriction:

- Quantity Limits: 20mg/kg/day

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Hyperphenylalaninemia due to PKU**, approve if:
  - Patient is on a Phe-restricted diet
  - Prescribed by or in consultation with a metabolic or genetic disease specialist
  - Recent (within 90 days) Phe blood level is > 360 µmols/L
  - Not to be used in conjunction with Palynziq
  - Dose does not exceed 20 mg/kg per day
  - If the prescription is written for Javygtor, there is documentation of trial and failure to use generic sapropterin

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is currently receiving medication or has previously met all initial approval criteria
- Member is responding positively to therapy as demonstrated by a reduction in Phe (phenylalanine) blood levels since initiation of therapy
- If request is for a dose increase, new dose does not exceed 20 mg/kg per day

References: N/A

Last review/revision date: 10/2022

Sargramostin (Leukine)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Acute myelogenous leukemia
- Allogeneic or autologous bone marrow transplantation
- Autologous peripheral blood progenitor cell mobilization and collection
- Autologous peripheral blood progenitor cell and bone marrow transplantation
- Hematopoietic radiation injury syndrome

Prescribing Restriction:

- Quantity Limit*: 250mcg/day (#10 per 28 days)
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myelogenous Leukemia**, approve if:
  - Patient is 55 years of age older
  - Patient has received or is currently receiving induction chemotherapy for AML
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Allogeneic or Autologous Bone Marrow Transplantation,** approve if:
  - Patient is 2 years of age or older
  - Patient has undergone allogeneic or autologous bone marrow transplantation
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Autologous Peripheral Blood Progenitor Cell Mobilization and Collection,** approve if:
  - Patient is 18 years of age or older
  - Patient is undergoing autologous hematopoietic stem cell transplantation
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation**, approve if:
  - Patient is 2 years of age or older

Sargramostin (Leukine)

- Patient has received autologous peripheral blood progenitor cell transplantation or bone marrow transplantation
- Patient has a confirmed diagnosis of acute lymphoblastic leukemia (ALL), Hodgkin lymphoma (HL), or non-Hodgkin lymphoma (NHL), confirmed by an FDA-approved test
- Prescribed dose is less than or equal to the FDA-approved maximum dose

- For the diagnosis of **Acute Hematopoietic Radiation Injury Syndrome**, approve if:
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 6/2022

Sarilumab (Kevzara)

Therapeutic Category: *Antirheumatic, Disease Modifying; Interleukin-6 Receptor Antagonist; Monoclonal Antibody*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis

Prescribing Restrictions:

- Quantity Limit: Up to 200 mg (#1.140 ml) every 2 weeks
- Prescriber restriction: Rheumatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e, drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

Sarilumab (Kevzara)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2023

Satralizumab (Enspryng)

Specific Therapeutic Class: *Monoclonal antibody, IL-6 antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Neuromyelitis Optica spectrum disorder

Prescribing Restriction:

- Quantity Limit*:
  - Initial: #3 per 28 days
  - Continuation: #1 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Neuromyelitis Optica Spectrum Disorder**, approve if:
  - Patient is 18 years of age or older
  - Patient is anti-aquaporin-4 (AQP4) antibody positive confirmed by an FDA-approved test
  - Patient does not have an active infection
  - Documentation is submitted for a negative hepatitis B and tuberculous screening
  - The prescribed dose is 120mg SQ at weeks 0,2,4 followed by 120mg every 4 weeks

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Dose is appropriate
- Patient does not have an active infection and will continue to be screened for hepatitis B and tuberculosis
- Patient has not experienced an elevation is AST or ALT greater than 5 times the ULN

References: N/A

Last review/revision date: 10/2023

Secukinumab (Cosentyx)

Therapeutic Category: *Anti-interleukin 17A Monoclonal Antibody; Antipsoriatic Agent; Monoclonal Antibody*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Ankylosing spondylitis
- Axial spondyloarthritis
- Enthesitis-related arthritis
- Hidradenitis Suppurativa
- Plaque psoriasis
- Psoriatic arthritis

Prescribing Restrictions:

- Quantity Limit:
  - Ankylosing spondylitis, Axial spondyloarthritis, psoriatic arthritis, Enthesitis-related arthritis : #4/28 days x 1 fill, then #1/28 days
  - Hidradenitis Suppurativa, Plaque psoriasis: 300mg once weekly at weeks 0, 1,2,3, and 4 followed by 300mg every 4 weeks
- Prescriber restriction: Rheumatologist or Dermatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID

- For diagnosis of **Axial Spondylarthritis**, approve if:
  - Patient is 18 years of age or older
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID

- For diagnosis of **Plaque Psoriasis**, approve if:

Secukinumab (Cosentyx)

- Patient is 6 years of age or older
- Patient has diagnosis of chronic moderate to severe plaque psoriasis
- Request is for subcutaneous administration (self-administration or by caregiver at home)
- Drug is being prescribed by a dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 of the following alternatives
  - Topical steroids
  - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
  - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
  - Cyclosporine
  - Acitretin (Soriatane)
  - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 2 years of age or older
  - Diagnosis of psoriatic arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids

- For diagnosis of **Enthesitis-related Arthritis**, approve if:
  - Patient is between 4 and 17 years of age
  - Patient has diagnosis of Enthesitis-related arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent

- For diagnosis of **Hidradenitis Suppurativa**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of moderate to severe hidradenitis suppurativa (Hurlet stage II and III)
  - Request is for subcutaneous administration (self-administration or by caregiver at home)

Secukinumab (Cosentyx)

- Drug has been prescribed by or is currently being supervised by a Dermatologist
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use of one or more conventional therapies for hidradenitis suppurativa such as acitretin, isotretinoin, alitretinoin, hormonal therapy, and systemic antibiotics
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 2/2024

Selegiline (Zelapar)

Specific Therapeutic Class: *Anti-Parkinson Agent, MAO Type B Inhibitor; Antidepressant, Monoamine Oxidase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Parkinson's Disease

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction:

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Parkinson's Disease,** approve if:
  - The patient is 18 years of age or older
  - The requested agent will be used in combination with carbidopa/levodopa
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use selegiline capsules or rasagiline

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improvement in symptoms

References: N/A

Last review/revision date: 1/2023

Selexipag (Uptravi)

Specific Therapeutic Class: *Prostacyclin; Prostacyclin IP Receptor Agonist; Vasodilator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary arterial hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Pulmonary arterial hypertension (PAH),** approve if:
     - Patient is 18 years of age or older
     - Patient has a diagnosis of PAH confirmed by RHC
     - There is documentation that the patient has WHO functional class (FC) II or III symptoms

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Last review/revision date: 6/2024

Selinexor (Xpovio)

Specific Therapeutic Class: *Antineoplastic Agent, Nuclear Export Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Diffuse large B-cell lymphoma, relapsed or refractory
- Multiple myeloma, relapsed or refractory
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Diffuse Large B-cell Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient had relapsed or refractory disease
  - Patient has received at least 2 lines of previous chemotherapy

- For the diagnosis of **Multiple Myeloma,** approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - All of the following:
      a. Patient has received at least 1 prior chemotherapy regimen
      b. The requested agent will be used in combination with bortezomib and dexamethasone
    - All of the following:
      a. Patient has relapsed or refractory disease
      b. Patient has received at least four prior therapies
      c. Disease is refractory to at least two proteasome inhibitors

Selinexor (Xpovio)

d. Disease is refractory to at least two immunomodulatory agents
e. Disease is refractory to an anti-CD38 monoclonal antibody
f. Requested agent will be used in combination with dexamethasone

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Selpercatinib (Retevmo)

Specific Therapeutic Class: *Antineoplastic Agent, RET Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer
- Thyroid cancer
- Solid tumors
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient is RET fusion positive confirmed by an FDA approved test

- For the diagnosis of **Solid Tumors,** approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient has a RET gene fusion confirmed by an FDA-approved test
  - The patient has experienced progression on or following prior systemic treatment
  - There are no satisfactory alternative options for therapy

- For the diagnosis of **Thyroid Cancer,** approve if:
  - Patient is 12 years of age or older

Selpercatinib (Retevmo)

- One of the following:
  - All of the following:
    a. Patient has advanced or metastatic medullary thyroid cancer
    b. Patient has a RET-positive mutation confirmed by an FDA-approved test
    c. Patient requires systemic therapy
  - All of the following:
    a. Patient has advanced or metastatic thyroid cancer
    b. Patient is RET fusion positive confirmed by an FDA-approved test
    c. Patient requires systemic therapy
    d. Patient is radioactive iodine-refractory (if radioiodine is appropriate)

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Selumetinib (Koselugo)

Specific Therapeutic Class: *Antineoplastic Agent, MEK Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Neurofibromatosis type 1
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Neurofibromatosis Type 1**, approve if:
  - Patient is 2 years of age or older
  - Patient is symptomatic
  - Patient has plexiform neurofibromas (PN) that are inoperable

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Setmelanotide (Imcivree)

Specific Therapeutic Class: *Melanocortin Receptor Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 16 weeks
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.

Prescribing Restriction:

- Quantity Limit*: 9 vials per 30 days (3mg daily)
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Weight Management in Obesity**, approve if:
  - Patient is 6 years of age or older
  - One of the following:
    - Diagnosis of obesity due to:
      a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing
      b. Genetic testing demonstrates variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance
    - Clinical diagnosis of Bardet-Biedl syndrome (BBS) confirmed by genetic testing
  - Prescribed dose is less than or equal to 3mg daily

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- One of the following:
  - The is documentation of at least a 5% reduction in baseline body weight
  - There is documentation of at least a 5% reduction in BMI for patients with continued growth potential
- Prescribed dose is less than or equal to 3mg daily

References: N/A

Last review/revision date: 10/2022

Sevelamer Chloride (Renagel)

Specific Therapeutic Class: *Phosphate Binder*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hyperphosphatemia

Prescribing Restriction:

- Quantity Limit*: #270 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hyperphosphatemia**, approve if:
  - Patient has a diagnosis of chronic kidney disease and is receiving dialysis
  - Patient is 6 years of age or older
  - There is documentation of trial and failure (Phosphate level > 5.5 mg/dl) with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sevelamer carbonate (Renvela) and lanthanum (Fosrenol)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy and has maintained a serum phosphorus level < 5.5 mg/dL

References: N/A

Last review/revision date: 1/2024

Siponimod (Mayzent)

Specific Therapeutic Class: *Sphingosine 1-Phosphate (S1P) Receptor Modulator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Relapsing/remitting MS (RRMS)
- Secondary progressive MS (SPMS)

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Relapsing/Remitting MS (RRMS),** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - The patients CYP2C9 genotype has been confirmed prior to starting treatment
  - The patient does NOT have a CYP2C9*3/*3 genotype
  - If the patient has genotypes CYP2C9 *1/*3 or *2/*3, the prescribed quantity is less than 1mg per day
  - The patient does not have a history (within the last 6 months) of myocardial infarction, unstable
  - angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
  - The patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
  - The patient does not have significant QTc prolongation (QTc greater than 500 msec)

- For the diagnosis of **Secondary Progressive MS (SPMS)**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dimethyl fumarate OR glatiramer acetate
  - Will not be used in combination with any other disease-modifying MS agent
  - The patients CYP2C9 genotype has been confirmed prior to starting treatment
  - The patient does NOT have a CYP2C9*3/*3 genotype
  - If the patient has genotypes CYP2C9 *1/*3 or *2/*3, the prescribed quantity is less than 1mg per day
  - The patient does not have a history (within the last 6 months) of myocardial infarction, unstable

Siponimod (Mayzent)

- angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- The patient does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
- The patient does not have significant QTc prolongation (QTc greater than 500 msec)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 10/2023

Sirolimus (Hyftor)

Specific Therapeutic Class: *Immunosuppressant Agent; mTOR Kinase Inhibitor; Topical Skin Product*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Facial angiofibroma associated with tuberous sclerosis

Prescribing Restriction:

- Quantity Limit*: #300 grams per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Dermatologist or Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**
   - For the diagnosis of **Facial Angiofibroma associated with Tuberous Sclerosis**, approve if:
     - Patient is 6 years of age or older
     - Patient has a diagnosis of tuberous sclerosis confirmed by an FDA-approved test
     - Patient has 3 or more facial papules of angiofibroma confirmed by physical exam
     - Patient is not a candidate for surgery or laser therapy

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
   - Patient is stable and continuing the medication
   - There is documented symptom improvement from baseline

References: N/A

Last review/revision date: 8/2022

Sodium Oxybate (Xyrem)

Specific Therapeutic Class: *Central Nervous System Depressant*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Narcolepsy with excessive daytime sleepiness
- Narcolepsy with cataplexy

Prescribing Restriction:

- Quantity Limit*: #540 ml per 30 days
- Prescriber restriction: Prescriber is a Neurologist or sleep specialist, or documentation has been provided that prescriber has consulted with a Neurologist or sleep specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Narcolepsy with Excessive Daytime Sleepiness**, approve if:
  - Patient is ≥ 7 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two stimulants

- For the diagnosis of **Narcolepsy with Cataplexy,** approve if:
  - Patient is ≥ 7 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two stimulants and at least two of the following: SSRI, TCA, or venlafaxine

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

Sodium Oxybate (Xyrem)

- Documentation has been submitted indicating patient has clinically benefited from treatment (i.e., improvement on Epworth Sleepiness score or other documentation)
- For cataplexy, documentation has been provided that there has been a reduction in frequency of cataplexy attacks.

References: N/A

Last review/revision date: 10/2023

Sodium Oxybate ER (Lumryz)

Specific Therapeutic Class: *Central Nervous System Depressant*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Narcolepsy with excessive daytime sleepiness
- Narcolepsy with cataplexy

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescriber is a Neurologist or sleep specialist, or documentation has been provided that prescriber has consulted with a Neurologist or sleep specialist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Narcolepsy with Excessive Daytime Sleepiness**, approve if:
  - Patient is ≥ 18 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two stimulants
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic sodium oxybate

- For the diagnosis of **Narcolepsy with Cataplexy,** approve if:
  - Patient is ≥ 18 years of age
  - Sleep study has been done to confirm diagnosis of narcolepsy
  - If the patient has a history of substance abuse, documentation has been provided that provider has referred the patient for substance abuse disorder treatment
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two stimulants and at least two of the following: SSRI, TCA, or venlafaxine
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic sodium oxybate

Sodium Oxybate ER (Lumryz)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Documentation has been submitted indicating patient has clinically benefited from treatment (i.e., improvement on Epworth Sleepiness score or other documentation)
- For cataplexy, documentation has been provided that there has been a reduction in frequency of cataplexy attacks

References: N/A

Last review/revision date: 10/2023

Sodium Phenylbutyrate (Buphenyl, Pheburane, Olpruva)

Specific Therapeutic Class: *Urea Cycle Disorder (UCD) Treatment Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Urea cycle disorders

Prescribing Restriction:

- Quantity Limit*:
  - Tablets: #1200 per 30 days
  - Tablet pack: #180 per 30 days
  - Titration tablet pack: #270 per 30 days
  - Powder: #600 grams per 30 days
- Prescriber restriction: Prescribed by or in consultation with a specialist in metabolic diseases or a geneticist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Urea Cycle Disorders**, approve if:
  - The patient has a diagnosis of ONE of the following urea cycle disorders confirmed by FDA-approved enzymatic or genetic testing:
    - carbamoylphosphate synthetase I deficiency [CPSID]
    - ornithine transcarbamylase deficiency [OTCD]
    - argininosuccinic acid synthetase deficiency [ASSD]
    - argininosuccinic acid lyase deficiency [ASLD]
    - arginase deficiency [ARGD]
  - The patient has a diagnosis of hyperammonemia AND ALL of the following:
    - The patient has elevated ammonia levels according to the patient's age [Neonate: plasma ammonia level 150 µmol/L (>260 µg/dL) or higher; Older child or adult: plasma ammonia level >100 µmol/L (>175 µg/dL)]
    - The patient has a normal anion gap
    - The patient has a normal blood glucose level
  - The patient does not have acute hyperammonemia
  - The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and, if clinically appropriate, essential amino acid supplementation
  - The patient will be using the requested agent as adjunctive therapy to dietary protein restriction

Sodium Phenylbutyrate (Buphenyl, Pheburane, Olpruva)

- If the prescription is written for Pheburane or Olpruva, there is documentation of trial and failure to use generic Sodium Phenylbutyrate

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented improvement in ammonia levels from baseline

References: N/A

Last review/revision date: 8/2023

Sodium Phenylbutyrate-Taurursodiol (Relyvrio)

Specific Therapeutic Class: *Histone Deacetylase Inhibitor; Hydrophilic Bile Acid*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Amyotrophic Lateral Sclerosis (ALS)

Prescribing Restriction:

- Quantity Limit*: #56 per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Amyotrophic lateral sclerosis**, approve if:
  - Patient is 18 years of age or older
  - Patient has signs of lower motor neuron (LMN) degeneration confirmed by clinical, electrophysiological, or neuropathologic examination
  - Patient has signs of upper motor neuron (UMN) degeneration confirmed by clinical examination
  - Patient has progressive spread of signs within a region or to other regions and absence of both of the following:
    - Electrophysiological evidence of other disease processes that might explain the signs of LMN and/or UMN degenerations
    - Neuroimaging evidence of other disease processes that might explain the observed clinical and electrophysiological signs
  - Patient has a revised ALSFRS-R score with at least 2 points in each of the 12 items (total 48 points)
  - There is documentation of trial and failure or inadequate response with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use riluzole

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy
- Patient maintains a revised ALSFRS-R score with at least 2 points in each of the 12 items (total 48 points)

References: N/A

Last review/revision date: 10/2022

Sodium Zirconium Cyclosilicate (Lokelma)

Specific Therapeutic Class: *Antidote; Potassium Binder*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hyperkalemia

Prescribing Restriction:

- Quantity Limit*:
  - 5 gram pack: #96 per 30 days
  - 10 gram pack #34 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hyperkalemia**, approve if:
  - Patient is 18 years of age or older
  - Patient is not taking other medications known to cause hyperkalemia (ACE inhibitor, ARB, aldosterone antagonist, etc.)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sodium polystyrene sulfonate at up to maximally tolerated doses

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented improvement in serum potassium compared to baseline

References: N/A

Last review/revision date: 3/2022

Sofosbuvir (Sovaldi)

Specific Therapeutic Class: *Antihepaciviral, Polymerase Inhibitor (Anti-HCV); NS5B RNA Polymerase Inhibitor*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 24 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 3 years of age or older
  - Patient has viral genotype 1,2,3, or 4 confirmed by an FDA-approved test
  - If the patient has viral genotype 1 or 4, the patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glecaprevir/pibrentasvir (Mavyret)
  - The patient does not have decompensated cirrhosis

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Requested regimen and duration is appropriate per AASLD/IDSA guidelines

References: N/A

Last review/revision date: 8/2022

Sofosbuvir-Velpatasvir (Epclusa)

Specific Therapeutic Class: *Antihepaciviral, NS5A Inhibitor; Polymerase Inhibitor (Anti-HCV); NS5B RNA Polymerase Inhibitor*

Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 24 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 3 years of age or older
  - Patient has viral genotype 1,2,3,4,5, or 6 confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glecaprevir/pibrentasvir (Mavyret)
  - If the patient is post kidney transplant, they do not have decompensated cirrhosis

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Requested regimen and duration is appropriate per AASLD/IDSA guidelines

References: N/A

Last review/revision date: 8/2022

Sofosbuvir-Velpatasvir-Voxilaprevir (Vosevi)

Specific Therapeutic Class: *Antihepaciviral, NS5A Inhibitor; Polymerase Inhibitor (Anti-HCV); NS3/4A Inhibitor; NS5A Inhibitor; NS5B RNA Polymerase Inhibitor*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 24 weeks
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatitis C Viral Infection (HCV)

Prescribing Restriction:

- Quantity Limit*: #28 per 28 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Hepatitis C Viral Infection (HCV)**, approve if:
  - Patient is 18 years of age or older
  - Patient has viral genotype 1,2,3,4,5, or 6 confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use glecaprevir/pibrentasvir (Mavyret)
  - The patient does not have decompensated cirrhosis

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Requested regimen and duration is appropriate per AASLD/IDSA guidelines

References: N/A

Last review/revision date: 8/2022

Somapacitan-beco (Sogroya)

Specific Therapeutic Class: *Growth Hormone*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Pediatric growth hormone deficiency (GHD)
- Adult growth hormone deficiency

Prescribing Restriction:

- Quantity Limit*: A quantity sufficient to fulfill the prescribed dose for 30 days up to the FDA-approved maximum dose for the specific product prescribed
- Prescriber restriction: Endocrinologist, Pediatrician, or Nephrologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pediatric Growth Hormone Deficiency**, approve if:
  - Patient is 2.5 years of age or older
  - There is documentation of a subnormal GH response < 10 mg/mL by at least one provocative stimulation test (i.e., insulin-induced hypoglycemia, arginine, ARG-GHRH, ARG-LDOPA, GHRH)
  - The diagnosis has been confirmed by one of the following:
    - Severe short stature (defined as patient's height at ≥ 2 standard-deviation [SD] below the population mean)
    - Height velocity < 25th percentile
    - Patient's height ≥ 1.5 SD below the midparental height (avg of mother's and father's heights)
    - Patient's height ≥ 2 SD below the mean and a 1-year height velocity more than 1 SD below the mean for chronologic age or (in children 2 years of age or older) a 1- year decrease of more than 0.5 SD in height
    - In the absence of short stature, a 1-year height velocity more than 2 SD below the mean or a 2-year height velocity more than 1.5 SD below the mean (may occur in GHD manifesting during infancy or in organic, acquired GHD)
    - Signs indicative of an intracranial lesion
    - Signs of multiple pituitary hormone deficiencies
    - Neonatal symptoms and signs of GHD
  - Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) or patient has NOT reached final height

Somapacitan-beco (Sogroya)

- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope)

- For the diagnosis of **Adult Growth Hormone Deficiency**, approve if:
  - For hypopituitarism due to pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma, diagnosis has been confirmed by at least one subnormal provocative stimulation test (i.e., insulin-induced hypoglycemia, arginine, ARG-GHRH, ARG-LDOPA)
  - For childhood-onset growth hormone deficiency (GHD), patient has childhood-onset growth hormone deficiency (GHD) due to organic diseases (e.g., craniopharyngioma)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documented response to growth hormone therapy (e.g., IGF-1 level normalization, increase in height velocity defined by >2cm/year compared to that of previous year)

References: N/A

Last review/revision date: 6/2023

Somatrogon-ghla (Ngenla)

Specific Therapeutic Class: *Growth Hormone*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Pediatric Growth Hormone Deficiency

Prescribing Restriction:

- Quantity Limit*: #4.8ml per 28 days
- Prescriber restriction: Endocrinologist or Pediatrician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pediatric Growth Hormone Deficiency**, approve if:
  - Patient is 3 years of age or older
  - There is documentation of a subnormal GH response < 10 mg/mL by at least one provocative stimulation test (i.e., insulin-induced hypoglycemia, arginine, ARG-GHRH, ARG-LDOPA, GHRH)
  - The diagnosis has been confirmed by one of the following:
    - Severe short stature (defined as patient's height at ≥ 2 standard-deviation [SD] below the population mean)
    - Height velocity < 25th percentile
    - Patient's height ≥ 1.5 SD below the midparental height (avg of mother's and father's heights)
    - Patient's height ≥ 2 SD below the mean and a 1-year height velocity more than 1 SD below the mean for chronologic age or (in children 2 years of age or older) a 1- year decrease of more than 0.5 SD in height
    - In the absence of short stature, a 1-year height velocity more than 2 SD below the mean or a 2-year height velocity more than 1.5 SD below the mean (may occur in GHD manifesting during infancy or in organic, acquired GHD)
    - Signs indicative of an intracranial lesion
    - Signs of multiple pituitary hormone deficiencies
    - Neonatal symptoms and signs of GHD
  - Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) or patient has NOT reached final height
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope)

Somatrogon-ghla (Ngenla)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if: • Patient is stable and continuing the medication • There is documented response to growth hormone therapy (e.g., IGF-1 level normalization, increase in height velocity defined by >2cm/year compared to that of previous year)
References: N/A
Last review/revision date: 8/2023

Somatropin (Growth Hormone Preparations)

Specific Therapeutic Class: *Growth Hormone*
Formulary Status: Non-Formulary

- Formulary, PA required: Somatropin (Genotropin, Humatrope)
- Non-formulary, PA required: Somatropin (Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive, Norditropin, Norditropin Flexpro, Norditropin NordiFlex)

Coverage Duration:

- Initial: 6 months
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Pediatric growth hormone deficiency (GHD)
- Growth Failure due to Chronic Renal Insufficiency
- Short stature associated with Turner Syndrome, Prader-Willi Syndrome, Noonan syndrome, SHOX Deficiency
- Adult growth hormone deficiency
- HIV/AIDS-wasting syndrome
- Short Bowel Syndrome

Prescribing Restriction:

- Quantity Limit*: A quantity sufficient to fulfill the prescribed dose for 30 days up to the FDA-approved maximum dose for the specific product prescribed
- Prescriber restriction: Endocrinologist, Pediatrician, or Nephrologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pediatric Growth Hormone Deficiency**, approve if:
  - There is documentation of a subnormal GH response < 10 mg/mL by at least one provocative stimulation test (i.e., insulin-induced hypoglycemia, arginine, ARG-GHRH, ARG-LDOPA, GHRH)
  - The diagnosis has been confirmed by one of the following:
    - Severe short stature (defined as patient's height at ≥ 2 standard-deviation [SD] below the population mean)
    - Height velocity < 25th percentile
    - Patient's height ≥ 1.5 SD below the midparental height (avg of mother's and father's heights)
    - Patient's height ≥ 2 SD below the mean and a 1-year height velocity more than 1 SD below the mean for chronologic age or (in children 2 years of age or older) a 1- year decrease of more than 0.5 SD in height

Somatropin (Growth Hormone Preparations)

        - In the absence of short stature, a 1-year height velocity more than 2 SD below the mean or a 2-year height velocity more than 1.5 SD below the mean (may occur in GHD manifesting during infancy or in organic, acquired GHD)
        - Signs indicative of an intracranial lesion
        - Signs of multiple pituitary hormone deficiencies
        - Neonatal symptoms and signs of GHD
    - Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) or patient has NOT reached final height
    - If the request is for Somatropin (Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive, Norditropin, Norditropin Flexpro, Norditropin NordiFlex), there is of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope)

- For the diagnosis of **Growth Failure due to Chronic Renal Insufficiency**, approve if:
    - Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand)
    - Patient's height at is ≥ 2 standard-deviations (SD) below the mean height for normal children of the same age and gender
    - If the request is for Somatropin (Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive, Norditropin, Norditropin Flexpro, Norditropin NordiFlex), there is of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope).

- For the diagnosis of **Short Stature associated with Turner Syndrome, Prader-Willi Syndrome, Noonan Syndrome, SHOX Deficiency,** approve if:
    - Patient has short stature as defined associated with Turner Syndrome, Prader-Willi Syndrome, Noonan syndrome, or SHOX Deficiency confirmed by an FDA-approved test
    - Patient's epiphysis has NOT closed (as confirmed by radiograph of the wrist and hand) OR the patient has NOT reached final height
    - If the request is for Somatropin (Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive, Norditropin, Norditropin Flexpro, Norditropin NordiFlex), there is of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope).

- For the diagnosis of **Adult Growth Hormone Deficiency**, approve if:
    - For hypopituitarism due to pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma, diagnosis has been confirmed by at least one subnormal provocative stimulation test (i.e., insulin-induced hypoglycemia, arginine, ARG-GHRH, ARG-LDOPA)
    - For childhood-onset growth hormone deficiency (GHD), patient has childhood-onset growth hormone deficiency (GHD) due to organic diseases (e.g., craniopharyngioma)

Somatropin (Growth Hormone Preparations)

- If the request is for Somatropin (Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive, Norditropin, Norditropin Flexpro, Norditropin NordiFlex), there is of trial and failure with documented, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope).

- For the diagnosis of **HIV/AIDS-wasting Syndrome**, approve if:
  - Patient is on antiviral therapy
  - Patient meets at least one of the following:
    - 10% unintentional weight loss over 12 months
    - 7.5% unintentional weight loss over 6 months
    - 5% body cell mass (BCM) loss within 6 months
    - In men: BCM < 35% of total body weight and body mass index (BMI) < 27kg/m2
    - In women: BCM < 23% of total body weight and BMI < 27 kg/m2
    - BMI < 20kg/m2
  - Patient has had an inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants or anabolic steroids)
  - If the request is for Somatropin (Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive, Norditropin, Norditropin Flexpro, Norditropin NordiFlex), there is of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope).

- For the diagnosis of **Short Bowel Syndrome,** approve if:
  - Patient is currently on specialized nutritional support (i.e., consisting of high carbohydrate, low-fat diet)
  - If the request is for Somatropin (Nutropin, Nutropin AQ, Nutropin AQ NuSpin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive, Norditropin, Norditropin Flexpro, Norditropin NordiFlex), there is of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Somatropin (Genotropin, Humatrope).

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- There is documented response to growth hormone therapy (e.g., IGF-1 level normalization, increase in height velocity defined by >2cm/year compared to that of previous year)

References: N/A

Last review/revision date: 5/2022

Sonidegib (Odomzo)

Specific Therapeutic Class: *Antineoplastic Agent, Hedgehog Pathway Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Basal cell carcinoma, locally advanced
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Basal Cell Carcinoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced disease
  - One of the following:
    - Patient has disease recurrence following surgery or radiation therapy
    - Patient is not a candidate for surgery or radiation therapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Sonidegib (Odomzo)

Last review/revision date: 10/2022

Sorafenib (Nexavar)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hepatocellular carcinoma
- Renal cell carcinoma, advanced
- Thyroid carcinoma, differentiated
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hepatocellular Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has unresectable disease

- For the diagnosis of **Renal Cell Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced disease
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sunitinib

- For the diagnosis of **Thyroid Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has locally recurrent or metastatic, progressive, differentiated disease

Sorafenib (Nexavar)

- Disease is refractory to radioactive iodine treatment

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2022

Sotatercept (Winrevair)

Specific Therapeutic Class: *Activin A Receptor IIA Ligand; Activin Ligand Trap, Activin Signaling Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Pulmonary arterial hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #2 vials (45mg or 60mg) every 3 weeks
- Prescriber restriction: Pulmonologist or Cardiologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Pulmonary Arterial Hypertension (PAH),** approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of PAH confirmed by RHC
  - There is documentation that the patient has WHO functional class (FC) II or III symptoms
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ambrisentan (Letairis), bosentan (Tracleer), or macitentan (Opsumit)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use one of the following:
    - A PDE5 inhibitor [sildenafil (Revatio) or tadalafil (Adcirca)]
    - A soluble guanylate cyclase stimulator [riociguat (Adempas)]
  - There is documentation that the patient will continue PAH background therapy unless not tolerated
  - Patient has a baseline platelet count ≥50,000/mm^3

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Sotatercept (Winrevair)

Last review/revision date: 6/2024

Sotorasib (Lumakras)

Specific Therapeutic Class: *Antineoplastic Agent, KRAS Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient has a KRAS G12C mutation confirmed by an FDA approved test
  - Patient has received at least one prior systemic chemotherapy regimen

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Sparsentan (Filspari)

Specific Therapeutic Class: *Angiotensin II Receptor Blocker; Endothelin Receptor Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Primary immunoglobulin A nephropathy

Prescribing Restriction:

- Quantity Limit*: #30 tablets per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Nephrologist
- **Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous and current therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Primary Immunoglobulin A Nephropathy**, approve if:
  - Patient is 18 years of age or older
  - Patient has primary immunoglobulin A nephropathy (IgAN) confirmed by biopsy
  - Patient has a baseline eGFR ≥30 mL/min/1.73 m^2
  - Patient has baseline proteinuria defined as ≥1 gram of protein/day
  - Patient is at risk for disease progression defined by a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g
  - There is documentation of trial and failure for at least 12 weeks with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use a maximized stable dose of renin-angiotensin-aldosterone system (RAAS) inhibitors (ACE inhibitor or ARB), defined as at least 50% of maximum labeled dose
  - Patient is not and will not be prescribed renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, or aliskiren while taking the requested agent
  - Patient is not pregnant

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improvement in proteinuria from baseline

References: N/A

Last review/revision date: 10/2023

Step Therapy Exception

Formulary Status: Formulary, Non-Formulary, PA/step required
**For drugs without specific criteria*

Coverage Duration: 1 year

Diagnosis Considered for Coverage:

- FDA approved indications
- See off-label criteria

Prescribing Restriction:

- Quantity Limit*: As requested not to exceed FDA approved or off-label dose

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Supporting documentation

Coverage Criteria:

I. **Initiation of Therapy:**

- Approve if:
  - Provider has demonstrated knowledge of step therapy requirements
  - One of the following:
    - Medical justification for why required step therapy drug(s) would be ineffective or have the potential to cause harm or deterioration of the member's condition
    - Medical justification for why the requested drug would be superior to the required prerequisite trail(s) with formulary drug(s)

I. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 12/2022

Stiripentol (Diacomit)

Specific Therapeutic Class: *Antiseizure Agent, Miscellaneous*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Dravet syndrome-associated seizures

Prescribing Restriction:

- Quantity Limit*: 180 per 30 days
- Prescriber restriction: Pediatrician or Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Dravet syndrome-associated seizures,** approve if:
  - Patient has a diagnosis of Dravet syndrome confirmed by an FDA-approved test
  - Patient is 6 months of age or older
  - Patient weighs at least 7kg
  - The requested agent will be used in combination with clobazam

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 7/2022

Succimer (Chemet)

Specific Therapeutic Class: *Antidotes - Metallic Poison*
Formulary Status: Formulary, PA required

Coverage Duration: Up to 19 days

Diagnosis Considered for Coverage:

- Lead poisoning
- Other Diagnoses: Follow off-label criteria

Prescribing Restriction:

- Quantity Limit:
  - Age 12 months to less than 18 years: 10 mg/kg/dose (or 350 mg/m2/dose) every 8 hours for 5 days followed by 10 mg/kg/dose (or 350 mg/m2/dose) every 12 hours for 14 days. Maximum: 500 mg/dose
  - Age 18 years or older: 10mg-30mg/kg/day for 5 days

Clinical Information Required for Review:

- Diagnosis
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Lead Poisoning**, approve if:
  - Treatment plan by or in consultation with a toxicologist or clinician who has experience with chelating agents
  - Blood lead level (BLL) > 45 mcg/dL in children and > 50 mcg/dL with significant symptoms or > 100 mcg/dL with or without symptoms in adults

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Repeat treatment course is required per PA request

References: N/A

Last review/revision date: 10/2022

Sucroferric Oxyhydroxide (Velphoro)

Specific Therapeutic Class: *Phosphate Binder*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Hyperphosphatemia

Prescribing Restriction:

- Quantity Limit*: #180 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hyperphosphatemia**, approve if:
  - Patient has a diagnosis of chronic kidney disease and is receiving dialysis
  - Patient is 18 years of age or older
  - One of the following:
    - Phosphate level > 5.5 mg/dl on sevelamer carbonate (Renvela)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sevelamer carbonate (Renvela)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient meets initiation of therapy criteria

References: N/A

Last review/revision date: 11/2022

Sunitinib (Sutent)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Gastrointestinal stromal tumor
- Pancreatic neuroendocrine tumors
- Renal cell carcinoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Gastrointestinal Stromal Tumor,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use imatinib

- For the diagnosis of **Pancreatic Neuroendocrine Tumor,** approve if:
  - Patient is 18 years of age or older
  - Patient has progressive and well-differentiated disease
  - Patient has unresectable locally advanced or metastatic disease

- For the diagnosis of **Renal Cell Carcinoma,** approve if:
  - Patient is 18 years of age or older
  - One of the following:

Sunitinib (Sutent)

- Patient has relapsed or unresectable disease
- Requested agent will be used as an adjunctive treatment for high risk of disease recurrence following a nephrectomy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2022

Tafamidis (Vyndamax, Vyndaqel)

Specific Therapeutic Class: *Transthyretin Stabilizer*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Amyloid cardiomyopathy

Prescribing Restriction:

- Quantity Limit*:
- Tafamidis (Vyndamax): #30 per 30 days
- Tafamidis (Vyndaqel): #120 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Cardiologist or a physician who specializes in the treatment of amyloidosis

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Amyloid Cardiomyopathy**, approve if:
  - Patient is ≥ 18 years
  - There is documentation of amyloid deposits on biopsy analysis from cardiac or non-cardiac sites
  - There is documentation of cardiac involvement confirmed by echocardiography or cardiac magnetic resonance imagining
  - For members with hereditary ATTR-CM, there is documentation of a mutation of the TTR gene confirmed by an FDA-approved test
  - For members with wild type ATTR-CM, there is documentation of transthyretin precursor proteins confirmed by immunohistochemical analysis, scintigraphy, or mass spectrometry
  - Patient has documented clinical symptoms of New York Heart Association Class I, II, or III heart failure (ex-dyspnea, fatigue, peripheral edema)
  - Prescriber has attested member is not and will not be prescribed tetramer stabilizers
  - Patient does not have a history of heart or liver transplant

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has not received a liver transplant

Tafamidis (Vyndamax, Vyndaqel)

- Patient is responding positively to therapy including but not limited to improvement in any of the following parameters:
  - Improved 6-minute walk test
  - Improvement in Kansas City Cardiomyopathy Questionnaire-Overall Summary
  - Decreased cardiovascular related hospitalizations
  - Improvement in NYHA classification
  - Improved ventricular stroke volume
  - Improved NT-proBNP level

References: N/A

Last review/revision date: 4/2022

Talazoparib (Talzenna)

Specific Therapeutic Class: *Antineoplastic Agent, PARP Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast cancer, locally advanced or metastatic
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient has a BRCA-positive mutation confirmed by an FDA-approved test
  - Patient is HER2-negative confirmed by and FDA-approved test

- For the diagnosis of **off-label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Tapentadol (Nucynta)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status: Formulary

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
    - Indication of chronic cancer pain
    - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
    - There is documented failure despite compliance to long-acting opiates
    - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

Tapentadol (Nucynta)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 8/2023

Tapentadol ER (Nucynta ER)

Specific Therapeutic Class: *Analgesics: Opiates, Long Acting*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days

**NOTE: doses above quantity limits are allowed for cancer pain*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use ALL of the following alternatives at an adequate (equianalgesic) dose
    - Oxymorphone immediate release
    - Morphine sulfate ER tablets (MS Contin) or capsules (Kadian)
    - Fentanyl patches (Duragesic) AND Oxycodone ER (Oxycontin)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 1/2023

Tapinarof (Vtama)

Specific Therapeutic Class: *Aryl Hydrocarbon Receptor Agonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: 3 months

Diagnosis Considered for Coverage:

- Psoriasis

Prescribing Restriction:

- Quantity Limit*: #60 grams per 28 days
- Prescriber restriction: Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 of the following alternatives:
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- There is documentation submitted to support the need of ongoing therapy beyond 12 weeks

References: N/A

Tapinarof (Vtama)

Last review/revision date: 6/2022

Tazemetostat (Tazverik)

Specific Therapeutic Class: *Antineoplastic Agent, EZH2-Inhibitor, Histone Methyltransferase (HMT) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Epithelioid sarcoma, metastatic or locally advanced
- Follicular lymphoma, relapsed/refractory
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Epithelioid Sarcoma**, approve if:
  - Patient is 16 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient is not eligible for complete resection

- For the diagnosis of **Follicular Lymphoma** , approve if:
  - Patient is 18 years of age or older
  - Patient has relapsed or refractory disease
  - One of the following:
    - Patient is positive for an EZH2 mutation confirmed by an FDA-approved test AND patient has received at least 2 prior systemic therapies
    - Patient has no satisfactory alternative treatment options

- For the diagnosis of **off-label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)

Tazemetostat (Tazverik)

- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Tbo-Filgrastim (Granix)

Specific Therapeutic Class: *Colony Stimulating Factor; Hematopoietic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Acute myeloid leukemia following induction or consolidation chemotherapy
- Bone marrow transplantation
- Chemotherapy-induced myelosuppression in nonmyeloid malignancies
- Peripheral blood progenitor cell collection and therapy
- Severe chronic neutropenia

Prescribing Restriction:

- Quantity Limit*:
  - 300/0.5 ml syringe: up to 7 ml per 28 days (should be billed in increments of 0.5 ml)
  - 480/0.8 ml syringe: up to 11.2 ml per 28 days (should be billed in increments of 0.8 ml)
- Prescriber restriction: Prescription written or currently being supervised by a Hematologist or an Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the **Diagnoses listed in "Diagnosis Considered for Coverage"** above, approve if:
  - Patient is currently being treated by a Hematologist or Oncologist
  - Prescribed dose is less than or equal to the FDA-approved maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 6/2022

Teduglitide (Gattex)

Specific Therapeutic Class: *Glucagon-Like Peptide-2 (GLP-2) Analog*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Short bowel syndrome

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Gastroenterologist or Pediatrician

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Short bowel Syndrome,** approve if:
  - Patient is 1 year of age or older
  - Patient has a diagnosis of short bowel syndrome confirmed by an FDA-approved test
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use loperamide, diphenoxylate, and oral rehydration solution
  - The patient is currently receiving parenteral nutrition/intravenous fluids (PN/IV) at least 3 days per week
  - The patient has had a colonoscopy within the last 6 months and if polyps were present at this colonoscopy, the polyps were removed
  - The prescribed dose is less than or equal to the FDA-labeled maximum dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- If the patient is using parenteral nutrition/intravenous fluids (PN/IV), the patient has had at least a 20% reduction from baseline in PN/IV fluid volume
- The prescribed dose is less than or equal to the FDA-labeled maximum dose

References: N/A

Last review/revision date: 10/2023

Telotristat Ethyl (Xermelo)

Specific Therapeutic Class: *Tryptophan Hydroxylase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Carcinoid syndrome diarrhea

Prescribing Restriction:

- Quantity Limit*: #90 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Carcinoid Syndrome Diarrhea,** approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use an SSA (e.g., octreotide, lanreotide) at up to maximally indicated doses
  - The requested agent is prescribed in combination with an SSA unless contraindicated or clinically significant adverse effects are experienced

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient is responding positively to therapy
- Patient continues to have diarrhea

References: N/A

Last review/revision date: 11/2022

Tenapanor (Ibsrela, Xphozah)

Specific Therapeutic Class: *Sodium/Hydrogen Exchanger 3 (NHE3) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Irritable bowel syndrome with constipation (IBS-C) (Ibsrela only)
- Hyperphosphatemia in chronic kidney disease (Xphozah only)

Prescribing Restriction:

- Quantity Limit*: #60 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Irritable Bowel Syndrome with Constipation (IBS-C)**, approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of IBS-C confirmed by FDA-approved criteria
  - Patient has less than 3 complete spontaneous bowel movements per week AND less than or equal to 5 spontaneous bowel movements per week
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following: Lubiprostone, Linzess, or Trulance
  - Patient does not have mixed IBS (IBS-M)
  - Patient does not have a known or suspected mechanical gastrointestinal obstruction
  - Prescription is written for Ibsrela or its generic if applicable

- For the diagnosis of **Hyperphosphatemia in chronic kidney disease,** approve if:
  - Patient is 12 years of age or older
  - Patient has a diagnosis of chronic kidney disease and is receiving dialysis
  - There is documentation of trial and failure (Phosphate level > 5.5 mg/dl) with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sevelamer carbonate (Renvela) and lanthanum (Fosrenol)
  - Prescription is written for Xphozah or its generic if applicable

Tenapanor (Ibsrela, Xphozah)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For the diagnosis of irritable bowel syndrome with Constipation (IBS-C):
  - Patient has experienced and maintained an improvement in the number of complete spontaneous bowel movements per week AND spontaneous bowel movements per week compared to baseline
- For the diagnosis of hyperphosphatemia in chronic kidney disease:
  - Patient is responding positively to therapy and has maintained a serum phosphorus level < 5.5 mg/dL

References: N/A

Last review/revision date: 1/2024

Tepotinib (Tepmetko)

Specific Therapeutic Class: *Antineoplastic Agent, MET Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Non-small cell lung cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient has mesenchymal-epithelial transition (MET) exon 14 skipping alterations confirmed by an FDA-approved test
- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Teriparatide (Forteo)

Standard/Specific Therapeutic Class: Miscellaneous, Bone Formation Stimulation Agents, Parathyroid Hormone
Formulary Status: Non-formulary, PA Required

Coverage Duration: 2 years

Diagnosis Considered for Coverage:

- Osteoporosis

Prescribing Restriction

- Quantity Limit*: #2.4 ml per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Dose
- T-score
- Fracture history

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Osteoporosis**, approve if:
  - Patient is 18 years of age or older
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., inability to swallow, drug interaction, allergy, adverse reaction, etc.) to use **at least one bisphosphonate** and denosumab (Prolia)
  - T-score < 2.5 OR T-score -1.0 and -2.5 with high risk of facture or history of fracture

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Medical justification provided for continuation of therapy beyond 2 years

References: N/A

Last review/revision date: 02/2022

Tesamorelin Injection (Egrifta)

Standard/Specific Therapeutic Class: Other Hormones, Growth Hormone Releasing Hormone (GNRH) and Analogs
Formulary Status: Non-formulary

Coverage Duration: 6 months

Diagnosis Considered for Coverage:

- HIV-Associated Visceral Adipose Tissue (VAT) Lipodystrophy

Prescribing Restriction

- Prescriber restriction: Endocrinologist or HIV specialist
- Quantity Limit*: 60 vials of 1mg Tesamorelin (Egrifta) OR 30 vials of 2mg Tesamorelin TM (Egrifta TM) per 30-day supply

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Previous therapy
- Concurrent therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For the **reduction of excess abdominal fat in patients diagnosed with HIV-Associated Lipodystrophy**, approve if:
  - Patient is 18 years of age or older
  - Physician attests patient does not currently have active malignancy and does not have disruption of the hypothalamic-pituitary axis
  - If the patient is a female of childbearing potential, there is documentation of a negative pregnancy test

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Documentation of clinical response based on decrease in waist circumference OR reduction in visceral adipose tissue on CT scan
- Drug is being requested at an FDA approved dose

References:

Last review/revision date: 11/2022

Tetrabenazine (Xenazine)

Specific Therapeutic Class: *Central Monoamine-Depleting Agent; Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Chorea associated with Huntington disease

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Prescriber is a Neurologist or Psychiatrist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Chorea associated with Huntington disease**, approve if:
  - Patient is 18 years of age or older
  - Patient has a diagnosis of Huntington's disease confirmed by an FDA-approved test
  - Documentation of baseline Total Maximal Chorea (TMC) score ≥ 8, or Total Functional Capacity (TFC) score ≥ 5 from UHDRS has been provided with the request

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Documentation was provided that demonstrates clinical symptom improvement (i.e., reduction of total chorea score from UHDRS)

References: N/A

Last review/revision date: 10/2023

Tezacaftor-Ivacaftor (Symdeko)

Specific Therapeutic Class: *Cystic Fibrosis Transmembrane Conductance Regulator Corrector; Cystic Fibrosis Transmembrane Conductance Regulator Potentiator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cystic fibrosis

Prescribing Restriction:

- Quantity Limit*: #56 tablets or packets per 28 days
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cystic Fibrosis**, approve if:
  - The patient is 6 years of age or older
  - The patient has a diagnosis of cystic fibrosis confirmed by an FDA-approved test
  - One of the following:
    - The patient is homozygous for the F508del mutation in the CFTR gene
    - The patient has a tezacaftor/ivacaftor-responsive mutation in the CFTR gene
  - The medication is being prescribed at a dose that is within FDA approved guidelines

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2022

Tezepelumab-ekko (Tezspire)

Specific Therapeutic Class: *Monoclonal Antibody; Monoclonal Antibody, Anti-Asthmatic*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Asthma

Prescribing Restriction:

- Quantity Limit*: 1.91ml per 28 days
- Prescriber restriction: Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Asthma**, approve if:
  - Patient is ≥ 12 years of age
  - Diagnosis of severe asthma confirmed by an FDA-approved test
  - Patient has experienced ≥ 2 exacerbations, within the last 12 months, requiring any of the following despite adherent use of controller therapy for at least 6 months (i.e., medium- to high-dose inhaled corticosteroid (ICS) plus either a long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindicated/intolerance):
    - Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
    - Urgent care visit or hospital admission
    - Intubation
  - The requested agent is prescribed concomitantly with an ICS plus either a LABA or LTRA

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Demonstrated continued adherence to asthma controller therapy that includes an ICS plus either an LABA or LTRA
- Patient is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second) since baseline, reduction in the use of rescue therapy)

References: N/A

Last review/revision date: 1/2023

Thalidomide (Thalomid)

Specific Therapeutic Class: *Angiogenesis Inhibitor; Antineoplastic Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Erythema nodosum leprosum
- Multiple myeloma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist, Hematologist, or Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Erythema Nodosum Leprosum**, approve if:
  - Request is for acute treatment of cutaneous disease
  - Patient has moderate to severe disease

- For the diagnosis of **Multiple Melanoma**, approve if:
  - Patient has newly diagnosed disease
  - The requested agent will be used in combination with dexamethasone

- For the diagnosis of **off-label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Thioguanine (Tabloid)

Specific Therapeutic Class: *Antineoplastic Agent, Antimetabolite, Antimetabolite (Purine Analog)*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute myeloid leukemia

Prescribing Restriction:

- Quantity Limit*: Authorized quantity sufficient for a 30 day supply
- Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia**, approve if:
  - Diagnosis is confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 7/2022

Tildrakizumab (Ilumya)

Therapeutic Category: *Antipsoriatic Agent; Interleukin-23 Inhibitor; Monoclonal Antibody*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Psoriasis

Prescribing Restrictions:

- Quantity Limit: 100 mg at weeks 0, 4, and then every 12 weeks thereafter
- Prescriber restriction: Dermatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least **3 of the following alternatives**
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]
    - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
    - Cyclosporine
    - Acitretin (Soriatane)
    - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to preexisting disease state - e.g., systemic lupus erythematous, cataracts)
    - Prior trial of disease modifying biologic
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), guselkumab (Tremfya), ixekizumab (Taltz), or risankizumab-rzaa (Skyrizi)

Tildrakizumab (Ilumya)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2023

Tiopronin (Thiola, Thiola EC)

Specific Therapeutic Class: *Urinary Tract Product*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Nephrolithiasis (cystine), prevention

Prescribing Restriction:

- Quantity Limit*: A quantity sufficient for a 30 day supply based on prescribed dose
- Prescriber restriction: Prescribed by or in consultation with a Nephrologist or Urologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Nephrolithiasis (cystine) Prevention**, approve if:
  - Patient is 9 years of age or older
  - A confirmed diagnosis of severe homozygous cystinuria with all of the following
    - 24-hour urine collection with urinary cystine > 500 mg/day
    - Patient is resistant to treatment with all of the following conservative measures
      a. High fluid intake of at least 3 L/day
      b. Urinary alkalization with potassium citrate to keep urine above pH 7
      c. Diet modification to restricted sodium and protein intake

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Patient has experienced improvement defined by urinary cysteine concentration is < 250 mg/L or reduction in cysteine stone production

References: N/A

Last review/revision date: 11/2022

Tivozanib (Fotivda)

Specific Therapeutic Class: *Antineoplastic Agent, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Renal cell carcinoma, advanced, relapsed or refractory
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Renal Cell Carcinoma**, approve if:
  - Patient is 18 years of age or older
  - Patient had relapsed or refractory disease
  - Patient has previously received at least 2 prior systemic therapies (including sunitinib)

- For the diagnosis of **off-label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Tobramycin Inh (Bethkis, Kitabis Pak, Tobi, Tobi Podhaler)

Specific Therapeutic Class: *Antibiotic, Aminoglycoside*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 3 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Cystic Fibrosis

Prescribing Restriction:

- Quantity Limit*:
  - Tobramycin 300 mg/4 ml nebulization solution (Bethkis): #224 ml per 56 days (300 mg/4ml twice daily; 28 days on, 28 days off therapy)
  - Tobramycin 28 mg caps (Tobi PodHaler): #224 caps per 56 days (4 caps twice daily; 28 days on, 28 days off therapy)
  - Tobramcyin 300 mg/5 ml solution (Tobi): #280 ml per 56 days (300 mg/5ml twice daily; 28 days on, 28 days off therapy)
  - Tobramycin 300 mg/5ml solution with nebulizer (Kitabis Pak): #280 ml per 56 days (300 mg/5ml twice daily; 28 days on, 28 days off therapy)
- Prescriber restriction: Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cystic Fibrosis**, approve if:
  - Patient is 6 years of age or older
  - The patient has a diagnosis of cystic fibrosis confirmed by an FDA-approved test
  - The patient has documented colonization with *P. aeruginosa* confirmed by an FDA-approved test
  - The medication is being prescribed at a dose that is within FDA approved guidelines
  - If the request is for Tobi Podhaler, there is documented trial and failure with Tobramycin nebulized solution

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Tobramycin Inh (Bethkis, Kitabis Pak, Tobi, Tobi Podhaler)

Last review/revision date: 7/2022

Tocilizumab (Actemra)

Therapeutic Category: *Antirheumatic, Disease Modifying; Interleukin-6 Receptor Antagonist*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Giant cell arteritis
- Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
- COVID-19 (Not covered)
- chimericChimeric antigen receptor T-cell therapy–associated cytokine release syndrome (Not Covered)

Prescribing Restrictions:

- Quantity Limit:
  - Rheumatoid Arthritis, Juvenile Idiopathic Arthritis
    - < 100 kg: #1.8 ml (2 syringes) per 28 days
    - ≥ 100 kg: #3.6 ml (4 syringes) per 28 days
  - Giant Cell Arteritis, Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD),
    - #3.6 ml (4 syringes) per 28 days
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist (see specific diagnosis in Coverage Criteria)

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:

Tocilizumab (Actemra)

        - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
            - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
        - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e, drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
    - Patient is between 2 and 17 years of age
    - Patient has diagnosis of juvenile idiopathic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use etanercept (Enbrel) AND Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Systemic Juvenile Idiopathic Arthritis**, approve if:
    - Patient is between 2 and 17 years of age
    - Patient has documented clinical diagnosis of juvenile idiopathic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Giant Cell Arthritis**, approve if:
    - Patient is 18 years of age or older
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 months of glucocorticoids

- For diagnosis of **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)**, approve if:

Tocilizumab (Actemra)

- Patient is 18 years of age or older
- The requested agent will not be administered IV
- The patient has a confirmed diagnosis of SSc-ILD
- There is early evidence of ILD progression documented
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use mycophenolate mofetil

- For diagnosis of **COVID-19**, deny

- For diagnosis of **Chimeric antigen receptor T-cell therapy–associated cytokine release syndrome**, deny

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 7/2023

Tofacitinib (Xeljanz) & Tofacitinib ER (Xeljanz XR)

Therapeutic Category: *Antirheumatic, Disease Modifying; Janus Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 6 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ulcerative colitis
- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis

Prescribing Restrictions:

- Quantity Limit:
  - Tofacitinib (Xeljanz): 60 tablets per 30 days
  - Tofacitinib ER (Xeljanz XR): 30 tablets per 30 days
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - Patient has been counseled on increased cardiovascular risks
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)

Tofacitinib (Xeljanz) & Tofacitinib ER (Xeljanz XR)

  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Diagnosis of psoriatic arthritis
  - Drug is being prescribed by a Rheumatologist or Dermatologist
  - Patient has been counseled on increased cardiovascular risks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use or Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Drug is being prescribed by a Gastroenterologist
  - Patient has been counseled on increased cardiovascular risks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is between 2 and 17 years of age
  - Patient has a confirmed diagnosis of Polyarticular Juvenile Idiopathic Arthritis
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - Patient has been counseled on increased cardiovascular risks
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent

Tofacitinib (Xeljanz) & Tofacitinib ER (Xeljanz XR)

  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of ankylosing spondylitis
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - Patient has been counseled on increased cardiovascular risks
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use or Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- Patient has not experienced an MI or stroke since the last review

References: N/A

Last review/revision date: 10/2023

Tolvaptan (Jynarque, Samsca)

Specific Therapeutic Class: *Vasopressin Antagonist*
Formulary Status: Formulary, PA required

Coverage Duration:

- Tolvaptan (Samsca):
  - Initial: 30 days
  - Continuing: 30 days
- Tolvaptan (Jynarque):
  - Initial: 6 months
  - Continuing: 12 months

Diagnosis Considered for Coverage:

- Autosomal dominant polycystic kidney disease (Jynarque)
- Hyponatremia (chronic), hypervolemic or euvolemic (Samsca)

Prescribing Restriction:

- Quantity Limit*:
  - Samsca:
    - #120/30 days
  - Jynarque:
    - 15mg: #60/30 days
    - 30mg: #30/30 days
- Prescriber restriction:

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Autosomal Dominant Polycystic Kidney Disease (Jynarque)**, approve if:
  - Patient is 18 years of age or older
  - The patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by ONE of the following:
    - Ultrasonography
    - MRI or CT scan
    - Genetic testing
  - ONE of the following:
    - The patients has had a sequential increase of >5% annually in TKV on imaging
    - Total kidney volume (TKV) >750 mL
    - Kidney length (KL) >16.5 cm
    - The patient has typical (Class 1) ADPKD and ONE of the following:
      a. The patient has been classified as 1C, 1D, or 1E using the Mayo ADPKD Classification assessment

Tolvaptan (Jynarque, Samsca)

b. The prescriber has provided documentation indicating the patient's ADPKD is rapidly progressing
- The patient has atypical (Class 2) ADPKD and the prescriber has provided documentation indicating the patient's ADPKD is rapidly progressing

- ONE of the following:
  - The patient is initiating therapy and ONE of the following:
    a. The patient's ALT, AST, bilirubin has been measured within the past 3 months prior to initiating therapy with the requested agent AND ONE of the following:
       i. The patient's most recent ALT, AST, and bilirubin levels are under the upper limit of normal (ULN)
       ii. The patient's most recent ALT, AST, and bilirubin levels are above the ULN and the prescriber has provided documentation in support of use with the requested agent with the elevated levels
  - The patient is continuing therapy and BOTH of the following:
    a. The patient has had ALT, AST, and bilirubin assessed in the past 3 months AND ONE of the following:
       i. The patient's most recent levels have NOT exceeded EITHER of the following:
          1. ALT or AST 2 times ULN
          2. ALT or AST 2 times the patient's baseline prior to initiating therapy with the requested agent
       ii. BOTH of the following:
          1. The most recent ALT or AST levels have exceeded 2 times ULN or 2 times the patient's baseline prior to initiating therapy with the requested agent
          2. The prescriber has provided documentation in support of use with the requested agent while at these elevated levels
    b. ONE of the following:
       i. The patient has never experienced ALT or AST levels exceeding 3 times ULN while on therapy with the requested agent
       ii. BOTH of the following:
          1. The prescriber has provided documentation indicating that the ALT or AST levels exceeding 3 times ULN while on therapy with the requested agent were due to cause unrelated to therapy with the requested agent
          2. patient's current ALT and AST levels have stabilized and are now below 3 times ULN AND
- ONE of the following:
  - The patient is not currently on therapy with another tolvaptan agent
  - The other tolvaptan agent will be discontinued prior to starting therapy with the requested agent

- For the diagnosis of **Hyponatremia (chronic), Hypervolemic or Euvolemic (Samsca)**, approve if:
  - There has been at least a 30 day lapse between previous treatment
  - Medication HAS or WILL BE initiated in the hospital where serum sodium can be monitored closely

Tolvaptan (Jynarque, Samsca)

- Is not used for the treatment of autosomal dominant polycystic kidney disease (ADPKD)
- Is not used for hypovolemic hyponatremia
- Patient does not have significant liver disease (including cirrhosis)
- Patient is not anuric
- May not be used in combination with tolvaptan (Jynarque)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 11/2022

Topotecan (Hycamtin)

Specific Therapeutic Class: *Antineoplastic Agent, Camptothecin, Topoisomerase I Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Small cell lung cancer, relapsed or progressive
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Small Cell Lung Cancer,** approve if:
  - Patient has had a prior complete or partial response and are at least 45 days from the end of first-line chemotherapy

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Tovorafenib (Ojemda)

Specific Therapeutic Class: *Antineoplastic Agent, BRAF Kinase Inhibitor, Type II RAF Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Pediatric low-grade glioma (pLGG)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
- Prescriber restriction: Oncologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pediatric low-grade glioma (pLGG)**, approve if:
  - Patient is 6 months of age or older
  - Patient has a BRAF alteration (e.g., BRAF fusion, or *BRAF V600* mutation) confirmed by an FDA-approved test
  - Patient has relapsed or refractory disease

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Tovorafenib (Ojemda)

Last review/revision date: 6/2024

Tralokinumab (Adbry)

Specific Therapeutic Class: *Interleukin-13 Antagonist; Monoclonal Antibody*
Formulary Status: Non-Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Atopic Dermatitis

Prescribing Restriction:

- Quantity Limit*:
  - Initial: #6 per 28 days
  - All subsequent fills: #4 per 28 days
- Prescriber restriction: Prescribed by or in consultation with a Dermatologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Atopic Dermatitis**, approve if:
  - Diagnosis of moderate to severe atopic dermatitis
  - Patient is 18 years of age or older
  - Body surface area (BSA) involvement > 10%
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 high potency topical corticosteroid AND topical calcineurin inhibitor (note: If patient meets approval criteria, a high-potency topical corticosteroid should be continued unless contraindicated)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use crisaborole (Eucrisa)
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use dupilumab (Dupixent)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of improvement in BSA involvement from baseline

References: N/A

Last review/revision date: 10/2023

Tramadol (Ultram)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*
Formulary Status:

- Formulary
  - tramadol (Ultram) 50 mg tablet (age minimum, 18 years)

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
    - Indication of chronic cancer pain
    - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)
    - There is documented failure despite compliance to long-acting opiates
    - Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

Tramadol (Ultram)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Tramadol-Acetaminophen (Ultracet)

Standard/Specific Therapeutic Class: *Narcotic Analgesics*

Formulary Status:

- Formulary
  - Tramadol/acetaminophen (Ultracet) 37.5-325 mg tablet (age minimum, 18 years)

Coverage Duration:

- Initial: day supply up to 7 days: one-time only
- Subsequent: quantity max #120 per 30 days: for duration requested up to one year

Diagnosis Considered for Coverage:

- Acute pain
- Chronic pain
- Other diagnoses: follow off-label criteria

Prescribing Restriction

- Quantity Limit*
  - *Initial fill day supply limit for new starts (no previous opioid claim in the past 180 days): 7 days*
  - *Subsequent fill quantity limit: #120 units per 30 days*

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Dose
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute or Chronic Pain**, approve if:
  - If request is for management of pain due to terminal illness and medication and dose requested is appropriate based on nature and severity of the diagnosis and not likely to cause harm, approve
  - For requests for short-acting opioid medication over the initial day supply limit of 7, approve if:
    - Medication is prescribed by a practitioner involved with care of the diagnosis provided
    - If quantity requested exceeds subsequent fill quantity limit, criteria for such a quantity are met with One of the following:
      a. Member has history of opioid use within the last 180 days
      b. Documented by requesting physician if member was on opioids out of state
      c. Indication of cancer pain
      d. Indication of palliative care
      e. Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
      f. Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration
  - For requests for formulary medication over subsequent fill quantity limit, approve if:
    - Use is short-term (i.e., less than 6 months requested) for post-operative or acute injury pain
    - Indication of chronic cancer pain
    - There is documented inability to use long-acting opiates (e.g., morphine sulfate ER tablets)

Tramadol-Acetaminophen (Ultracet)

- There is documented failure despite compliance to long-acting opiates
- Higher dose is needed as part of a protocol to taper to a lower dose or off long-acting opiates

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- For dose increases from previous approval to quantity > #120 per 30 days, criteria for subsequent fill quantity limit are met:
  - One of the following:
    - Member has history of opioid use within the last 180 days
    - Documented by requesting physician if member was on opioids out of state
    - Indication of cancer pain
    - Indication of palliative care
    - Indication of acute pain from a chronic diagnosis (i.e., sickle cell disease)
    - Expected duration of treatment is greater than 7 days based on indication, with documentation of indication and expected duration

References: N/A

Last review/revision date: 1/2023

Trametinib (Mekinist)

Specific Therapeutic Class: *Antineoplastic Agent, MEK Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Melanoma
- Non-small cell lung cancer (metastatic)
- Solid tumors (unresectable or metastatic)
- Anaplastic Thyroid cancer (locally advanced or metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Melanoma,** approve if:
  - Patient is 18 years of age or older
  - If the patient has unresectable or metastatic disease, both of the following:
    - Patient has a BRAF V600E or BRAF V600K mutation confirmed by an FDA-approved test
    - The requested agent will be used as monotherapy OR in combination with dabrafenib
  - If the patient has resectable disease, all of the following:
    - Patient has a BRAF V600E or BRAF V600K mutation confirmed by an FDA-approved test
    - Disease has lymph node involvement
    - The requested agent will be used in combination with dabrafenib
    - The requested agent will be used as adjuvant treatment following complete resection

- For the diagnosis of **Non-Small Cell Lung Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient has a BRAF V600E mutation confirmed by an FDA-approved test

Trametinib (Mekinist)

- The requested agent will be used in combination with dabrafenib

- For the diagnosis of **Solid Tumors,** approve if:
  - Patient is 6 years of age or older
  - Patient has unresectable or metastatic disease
  - Patient has a BRAF V600E mutation confirmed by an FDA-approved test
  - The requested agent will be used in combination with dabrafenib (Tafinlar)
  - Patient has progressed following previous treatment
  - No satisfactory alternative options are available
  - Patient does not have colorectal cancer

- For the diagnosis of **Anaplastic Thyroid Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has locally advanced or metastatic disease
  - Patient has a BRAF V600E mutation confirmed by an FDA-approved test
  - The requested agent will be used in combination with dabrafenib
  - There are no satisfactory locoregional treatment options

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 1/2023

Treprostinil (Tyvaso)

Standard/Specific Therapeutic Class: *Prostacyclin; Prostaglandin; Vasodilator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Re-authorization: 12 months

Diagnosis Considered for Coverage:

- Pulmonary Arterial Hypertension (PAH)
- Pulmonary hypertension associated with interstitial lung disease

Prescribing Restriction:

- Quantity Limit*:
  - Treprostinil (Tyvaso) Inhalation Starter Kit: #81.2 mL per 28 days, 1 fill only
  - Treprostinil (Tyvaso) Inhalation Refill Kit: #81.2 mL per 28 days
  - Treprostinil (Tyvaso) 1.74mg/2.9mL neb ampule: #81.2 mL per 28 days
  - Treprostinil (Tyvaso DPI) Maintenance Kits #112 per 28 days
  - Treprostinil (Tyvaso DPI) Titration Kits: #252 per 28 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information required for Review:

- Diagnosis
- Medical records
- Previous and current therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pulmonary Arterial Hypertension (PAH),** approve if:
  - Patient has a diagnosis of PAH confirmed by RHC
  - There is documentation that the patient has WHO functional class (FC) II or III symptoms

- For the diagnosis of **Pulmonary hypertension associated with interstitial lung disease (WHO group 3),** approve if:
  - Patient has pulmonary hypertension confirmed by RHC
  - Patient has interstitial lung disease confirmed by both of the following:
    - Computed Tomography
    - Hypoxia with a mPAP greater than 21mmHg and PVR of 3 WU or more

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

Treprostinil (Tyvaso)

- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Last review/revision date: 6/2024

Treprostinil ER (Orenitram)

Standard/Specific Therapeutic Class: *Prostacyclin; Prostaglandin; Vasodilator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Re-authorization: 12 months

Diagnosis Considered for Coverage:

- Pulmonary arterial hypertension (PAH)

Prescribing Restriction:

- Quantity Limit*: #60 tablets per 30 days
- Prescriber restriction: Cardiologist or Pulmonologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information required for Review:

- Diagnosis
- Medical records
- Previous and current therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Pulmonary arterial hypertension (PAH),** approve if:
  - Patient has a diagnosis of PAH confirmed by RHC
  - There is documentation that the patient has WHO functional class (FC) II or III symptoms
  - The patient does not have severe hepatic impairment

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvements in WHO FC symptoms, risk status, or exercise capacity

References: N/A

Last review/revision date: 6/2026

Tretinoin

Specific Therapeutic Class: *Antineoplastic Agent, Retinoic Acid Derivative*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute promyelocytic leukemia
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Acute Promyelocytic Leukemia** , approve if:
  - Requested agent will be used for induction therapy
  - Patient has French American British (FAB) classification M3 (including the M3 variant) characterized by t(15;17) translocation and/or PML/RARα gene presence confirmed by an FDA-approved test
  - If the patient is female, the patient is not pregnant

- For the diagnosis of **off-label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 11/2022

Trientine (Syprine, Clovique, Cuvrior)

Standard/Specific Therapeutic Class: Chelating Agent
Formulary Status: Formulary, PA required

Coverage Duration: Indefinite

Diagnosis Considered for Coverage:

- Wilson's Disease

Prescribing Restrictions

- Quantity Limits*:
  - Clovique & generic trientine: #240 per 30 days
  - Cuvrior: #300 per 30 days

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review

- Diagnosis
- Medical records
- Dose

Coverage Criteria:

I. **Initiation of Therapy**:

- For the diagnosis of Wilson's Disease, approve if:
  - Patient has a diagnosis of Wilsons disease confirmed by an FDA-approved test
  - If the request is for Clovique or generic trientine 250mg capsules, there is a documented intolerance of penicillamine
  - If the request is for 500mg capsules, there is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use 250mg capsules
  - If the request is for Cuvrior, both of the following
    - The patient is 18 years of age or older
    - The patient has documented tolerance with penicillamine
    - The patient has been decoppered

References: N/A

Last review/revision date: 10/2023

Trifluridine (Lonsurf)

Specific Therapeutic Class: *Antineoplastic Agent, Antimetabolite (Pyrimidine Analog); Thymidine Phosphorylase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Colorectal cancer (metastatic)
- Gastric cancer (metastatic)
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Colorectal Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient has been previously treated with a fluoropyrimidine-based, oxaliplatin-based, and irinotecan-based chemotherapy
  - Patient has been previously treated with an anti-VEGF biological therapy
  - If patient is RAS wild-type confirmed by an FDA-approved test, patient has been previously treated with an anti-EGFR therapy

- For the diagnosis of **Gastric Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has metastatic disease
  - Patient has been treated with at least two lines of previous chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan
  - If the patient is HER2 positive confirmed by an FDA-approve test, patient has been previously treated with an anti-HER2 therapy

Trifluridine (Lonsurf)

- For the diagnosis of **off-label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 11/2022

Triheptanoin (Dojolvi)

Specific Therapeutic Class: *Anaplerotic Agent; Nutritional Supplement*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: Indefinite

Diagnosis Considered for Coverage:

- Long-chain fatty acid oxidation disorders

Prescribing Restriction:

- Quantity Limit*: A sufficient quantity to fulfill a 30 day supply based on prescribed dose
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Long-Chain Fatty Acid Oxidation Disorders**, approve if:
  - The member has a diagnosis of a long-chain fatty acid oxidation disorder
  - The medication is prescribed and an appropriate dose

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at an appropriate dose

References: N/A

Last review/revision date: 11/2022

Trofinetide (Daybue)

Specific Therapeutic Class: *Glycine-Proline-Glutamate Analogs*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rett syndrome

Prescribing Restriction:

- Quantity Limit*: Quantity sufficient for a 30 day supply based on the following doses:
  - 12kg to <20kg: 6000mg twice daily
  - 20kg to <35kg: 8000mg twice daily
  - 35kg to <50kg: 10,000mg twice daily
  - Greater than or equal to 50kg: 12,000mg twice daily
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Rett Syndrome,** approve if:
  - Patient is 2 years of age or older
  - Patient weighs greater than or equal to 12kg
  - Patient has a *MECP2* gene mutation confirmed by an FDA-approved genetic test
  - One of the following:
    - Patient has all of the following:
      a. Partial or complete loss of acquired purposeful hand skills
      b. Partial or complete loss of acquired spoken language
      c. Gait abnormalities: impaired (dyspraxic) or absence of ability
      d. Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms
    - Patient has both of the following:
      a. Patient has at least 2 of the following:
         i. Partial or complete loss of acquired purposeful hand skills
         ii. Partial or complete loss of acquired spoken language
         iii. Gait abnormalities: impaired (dyspraxic) or absence of ability
         iv. Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms
      b. Patient has at least 5 of the following:

Trofinetide (Daybue)

i. Breathing disturbances when awake
ii. Bruxism when awake
iii. Impaired sleep pattern
iv. Abnormal muscle tone
v. Peripheral vasomotor disturbances
vi. Scoliosis/kyphosis
vii. Growth retardation
viii. Small cold hands and feet
ix. Inappropriate laughing/screaming spells
x. Diminished response to pain
xi. Intense eye communication ("eye pointing")

- The patient has a Clinical Severity Scale rating greater than or equal to 10

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of the need for continued therapy

References: N/A

Last review/revision date: 5/2023

Tucatinib (Tukaysa)

Specific Therapeutic Class: *Antineoplastic Agent, Anti-HER2, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Breast Cancer
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. **Initiation of Therapy:**

- For the diagnosis of **Breast Cancer**, approve if:
  - Patient is 18 years of age or older
  - Patient has advanced unresectable or metastatic disease
  - Patient is human epidermal growth factor receptor 2 (HER2)-positive confirmed by an FDA-approved test
  - The requested agent will be used in combination with trastuzumab and capecitabine
  - Patient has previously received at least 1 prior anti-HER2-based chemotherapy regimen

- For the diagnosis of **off-label indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Ubrogepant (Ubrelvy)

Specific Therapeutic Class: *Antimigraine Agent; Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist*
Formulary Status: Formulary

Coverage Duration:

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Prevention and treatment of migraines

Prescribing Restriction:

- Quantity Limit*: #10 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Prevention and treatment of Migraines,** approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - The prescribed quantity is less than or equal to #10 per 30 days
    - There is documentation of greater than 5 moderate to severe migraines within 30 days confirmed by medical records and the prescribed quantity is less than #30 per 30 days
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to us at least 2 injectable CGRPs

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication

References: N/A

Last review/revision date: 9/2023

Upadacitinib (Rinvoq LQ)

Therapeutic Category: *Antirheumatic Miscellaneous; Antirheumatic, Disease Modifying; Janus Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Psoriatic Arthritis
- Polyarticular juvenile idiopathic arthritis

Prescribing Restrictions:

- Quantity Limit: #360 per 30 days
- Prescriber restriction: Rheumatologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Psoriatic Arthritis**, approve if:
  - Patient is 2 years of age or older
  - Diagnosis of psoriatic arthritis
  - Drug is being prescribed by a Rheumatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
  - Patient is 2 years of age or older
  - Patient has diagnosis of juvenile idiopathic arthritis
  - Drug has been prescribed or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima)

Upadacitinib (Rinvoq LQ)

(Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. **Continuation of Therapy for EXISTING Members** (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:
- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- Patient has not experienced an MI or stroke since last review

References: N/A

Last review/revision date: 6/2024

Upadacitinib ER (Rinvoq)

Therapeutic Category: *Antirheumatic Miscellaneous; Antirheumatic, Disease Modifying; Janus Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Rheumatoid arthritis
- Psoriatic Arthritis
- Atopic Dermatitis
- Ulcerative Colitis
- Ankylosing Spondylitis
- Axial spondylarthritis
- Crohn's Disease
- Polyarticular juvenile idiopathic arthritis

Prescribing Restrictions:

- Quantity Limit: #30 per 30 days
- Prescriber restriction: Rheumatologist, Dermatologist, or Gastroenterologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Rheumatoid Arthritis**, approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of moderate to severe rheumatoid arthritis
  - Drug has been prescribed by or is currently being supervised by a Rheumatologist
  - There is documentation of trial and failure with documented compliance to at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent OR early RA [less than 6 months from diagnosis] with poor prognosis (e.g., boney erosions, rheumatoid nodules, positive rheumatoid factor, and severe functional limitation)
  - ONE of the following:
    - There is documentation of trial and failure with documented compliance with oral methotrexate with a weekly dose less than 15 mg
      - If the patient has documented inability to take oral methotrexate due to GI tolerability, they must meet criteria below
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication to use injectable methotrexate (note: If patient meets approval criteria, injectable methotrexate should be continued unless contraindicated)

Upadacitinib ER (Rinvoq)

    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Psoriatic Arthritis**, approve if:
    - Patient is 2 years of age or older
    - Diagnosis of psoriatic arthritis
    - Drug is being prescribed by a Rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

- For the diagnosis of **Atopic Dermatitis**, approve if:
    - Diagnosis of moderate to severe atopic dermatitis
    - Patient is 12 years of age or older
    - Body surface area (BSA) involvement > 10%
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, areas involving face, neck flexural, genital, or intertriginous areas etc.) to use at least 1 high potency topical corticosteroid AND topical calcineurin inhibitor (note: If patient meets approval criteria, a high-potency topical corticosteroid should be continued unless contraindicated)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use crisaborole (Eucrisa)
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use oral corticosteroids OR dupilumab (Dupixent)

- For diagnosis of **Ulcerative Colitis**, approve if:
    - Patient is 18 years of age or older
    - Patient has a confirmed diagnosis of Ulcerative Colitis
    - Drug is being prescribed by a Gastroenterologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids

Upadacitinib ER (Rinvoq)

    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Ankylosing Spondylitis**, approve if:
    - Patient is 18 years of age or older
    - Patient has diagnosis of ankylosing spondylitis
    - Drug has been prescribed by or is currently being supervised by a Rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Axial Spondylarthritis**, approve if:
    - Patient is 18 years of age or older
    - Patient has diagnosis of axial spondylitis
    - Drug has been prescribed by or is currently being supervised by a rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least ONE NSAID

- For diagnosis of **Crohn's Disease**, approve if:
    - Patient is 18 years of age or older
    - Patient has a diagnosis of moderate to severely active Crohn's Disease
    - Drug has been prescribed by or is currently being supervised by a Gastroenterologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use more conventional therapies for Crohn's Disease such as corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine.
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets this criteria if they have tried and failed Adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**, approve if:
    - Patient is 2 years of age or older
    - Patient has diagnosis of juvenile idiopathic arthritis
    - Drug has been prescribed or is currently being supervised by a Rheumatologist

Upadacitinib ER (Rinvoq)

- There is documentation of trial and failure with documented compliance to use at least one oral DMARD (e.g., methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide) or medical reason (intolerance, allergy, contraindication, etc.) for not utilizing DMARD agent
- There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

III. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose
- Patient has not experienced an MI or stroke since last review

References: N/A

Last review/revision date: 6/2024

Uridine Triacetate (Xuriden)

Specific Therapeutic Class: *Antidote; Endocrine and Metabolic Agent, Miscellaneous*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Hereditary orotic aciduria

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: Prescribed by or in consultation with specialist in genetic metabolic diseases

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Hereditary Orotic Aciduria**, approve if:
  - Diagnosis of Hereditary Orotic Aciduria confirmed by both of the following:
    - Megaloblastic anemia unresponsive to iron, folic acid, or vitamin B12
    - Excessive urinary excretion of orotic acid
  - All of the following baseline tests have been completed before initiation of treatment:
    - Complete blood count with differential
    - Urinalysis for orotic acid and orotidine levels
  - Prescription is written for Xuriden product

References: N/A

Last review/revision date: 11/2022

Ustekinumab (Stelara)

Therapeutic Category: *Antipsoriatic Agent; Interleukin-12 Inhibitor; Interleukin-23 Inhibitor; Monoclonal Antibody*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months (8 weeks for ulcerative colitis)
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Plaque psoriasis
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis

Prescribing Restrictions:

- Quantity Limit:
  - Crohn's disease
    - Maintenance only, 90 mg every 8 weeks
  - Plaque psoriasis
    - 100 kg or less: 45 mg at week 0, 4 and then 45 mg every 12 weeks
    - >100 kg: 90 mg at week 0, 4, and then 90 mg every 12 weeks
  - Psoriatic arthritis
    - 45 mg at week 0, 4 and then 45 mg every 12 weeks
    - Coexistent plaque psoriasis and >100 kg: 90 mg at week 0, 4, and then 90 mg every 12 weeks
  - Ulcerative Colitis
    - 90 mg every 8 weeks
- Prescriber restriction: Dermatologist or Gastroenterologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Plaque Psoriasis**, approve if:
  - Patient is 6 years of age or older
  - Patient has diagnosis of chronic moderate to severe plaque psoriasis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Dermatologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 3 of the following alternatives
    - Topical steroids
    - Topical medications [i.e., Dovonex (calcipotriene), Tazorac (tazarotene), anthralin or a coal tar preparation]

Ustekinumab (Stelara)

        - Methotrexate (inability to use examples include but not limited to history of liver or kidney disease, pregnancy, severe cytopenia, alcoholism)
        - Cyclosporine
        - Acitretin (Soriatane)
        - UVB phototherapy or PUVA (psoralen – oral or topical methoxsalen plus UVA therapy) (inability to use examples include but not limited to pregnancy, skin cancer, hypersensitivity due to pre-existing disease state - e.g., systemic lupus erythematous, cataracts)
        - Prior trial of disease modifying biologic
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), or risankizumab-rzaa (Skyrizi)

- For diagnosis of **Psoriatic Arthritis**, approve if:
    - Patient is 6 years of age or older
    - Diagnosis of psoriatic arthritis
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug is being prescribed by a Rheumatologist or Dermatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication with at least one oral DMARD (e.g., methotrexate) or inability to use DMARD (e.g., liver toxicity with methotrexate) OR predominantly axial symptoms (i.e., spinal column or sacral involvement) or active enthesitis (tendon swelling) and/or dactylitis (toe/finger swelling) with trial and failure of NSAIDS or steroids
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 2 of the following etanercept (Enbrel), Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar), secukinumab (Cosentyx), guselkumab (Tremfya), ixekizumab (Taltz), tofacitinib (Xeljanz), tofacitinib ER (Xeljanz XR), Risankizumab-Rzaa (Skyrizi), or upadacitinib (Rinvoq)

- For diagnosis of **Crohn's Disease**, approve if:
    - Patient is 6 years of age or older
    - Patient has a diagnosis of moderate to severely active Crohn's Disease
    - Request is for subcutaneous administration (self-administration or by caregiver at home)
    - Drug has been prescribed by or is currently being supervised by a Gastroenterologist or Rheumatologist
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use more conventional therapies for Crohn's Disease such as corticosteroids, azathioprine, mercaptopurine, methotrexate, or mesalamine.
    - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A

Ustekinumab (Stelara)

member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 6 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 10/2023

Valbenazine (Ingrezza)

Specific Therapeutic Class: *Central Monoamine-Depleting Agent; Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Tardive dyskinesia

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: Prescriber is a Neurologist or Psychiatrist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Tardive dyskinesia**, approve if:
  - Patient is 18 years of age or older
  - Documented baseline evaluation with one of the following scoring tools: Abnormal Involuntary Movement Scale (AIMS) > 10 OR Extrapyramidal Symptom Rating Scale (ESRS) > 20
  - Documentation of trial and failure with documented compliance or intolerance of contraindication to, or inability to use Deutetrabenazine (Austedo)

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Documentation was provided that demonstrates improvement

References: N/A

Last review/revision date: 9/2022

Vamorolone (Agamree)

Therapeutic Category: *Corticosteroid, Systemic*
Formulary Status: Non-Formulary

Coverage Duration

- Initial: 3 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Duchenne muscular dystrophy

Prescribing Restrictions:

- Quantity Limit: #225 ml per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Neurologist

Clinical Information Required for Review:

- Diagnosis and severity
- Medical records
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Duchenne Muscular Dystrophy,** approve if:
  - Patient is 2 years of age or older
  - Patient has diagnosis of Duchenne Muscular Dystrophy confirmed by an FDA-approved genetic test demonstrating a DMD gene mutation or muscle biopsy demonstrating a lack of muscle dystrophin
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use prednisone or prednisolone for at least 12 months
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic deflazacort

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline (improved strength and timed motor function, improved pulmonary function, etc)

References: N/A

Last review/revision date: 6/2024

Vandetanib (Caprelsa)

Specific Therapeutic Class: *Antineoplastic Agent, Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor, Vascular Endothelial Growth Factor (VEGF) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Thyroid cancer, medullary
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Medullary Thyroid Cancer,** approve if:
  - Patient is 18 years of age or older
  - Patient has unresectable locally advanced or metastatic disease
  - Patient has symptomatic or progressive disease

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Vedolizumab (Entyvio)

Therapeutic Category: *Gastrointestinal Agent, Miscellaneous; Monoclonal Antibody, Selective Adhesion-Molecule Inhibitor*
Formulary Status: Non-formulary

Coverage Duration

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Ulcerative colitis

Prescribing Restrictions:

- Quantity Limit: 1.36ml per 28 days
- Prescriber restriction: Gastroenterologist

Clinical Information Required for Review:

- Diagnosis and severity
- Previous therapy
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Ulcerative Colitis**, approve if:
  - Patient is 18 years of age or older
  - Patient has a confirmed diagnosis of ulcerative colitis
  - Request is for subcutaneous administration (self-administration or by caregiver at home)
  - Drug is being prescribed by a Gastroenterologist
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use sulfasalazine, mesalamine, azathioprine, 6-mercaptopurine or oral corticosteroids
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use Adalimumab-bwwd (Hadlima) (Note: A member meets the adalimumab criteria if they have tried and failed adalimumab (Humira) or another adalimumab biosimilar)
  - Patient has or will receive at least 2 IV doses (Note: approval for outpatient subcutaneous administration should be approved via this criteria before IV doses are given)

- For diagnosis of **Crohn's disease**, deny

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 10/2023

Vemurafenib (Zelboraf)

Specific Therapeutic Class: *Antineoplastic Agent, BRAF Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Melanoma
- Erdheim-Chester disease
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Melanoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has unresectable or metastatic disease
  - Patient has a BRAF V600E mutation confirmed by an FDA-approved test
  - Patient does not have wild-type BRAF confirmed by an FDA-approved test

- For the diagnosis of **Erdheim-Chester Disease,** approve if:
  - Patient is 18 years of age or older
  - Patient has a BRAF V600 mutation confirmed by an FDA-approved test

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert

Vemurafenib (Zelboraf)

- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2022

Venetoclax (Venclexta)

Specific Therapeutic Class: *Antineoplastic Agent; Antineoplastic Agent, BCL-2 Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Acute Myeloid Leukemia
- Chronic Lymphocytic Leukemia
- Small Lymphocytic Lymphoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Acute Myeloid Leukemia,** approve if:
  - Patient is 18 years of age or older
  - One of the following
    - Patient is 75 years of age or older
    - Patient has comorbidities that preclude the use of intensive induction chemotherapy
  - The requested agent will be used in combination with azacitidine, decitabine, or low-dose cytarabine

- For the diagnosis of **Chronic Lymphocytic Leukemia,** approve if:
  - Patient is 18 years of age or older

- For the diagnosis of **Small Lymphocytic Lymphoma,** approve if:
  - Patient is 18 years of age or older

- For the diagnosis of **Off-Label Indications**, approve if:

Venetoclax (Venclexta)

- Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
- Documentation provided of results of genetic testing where required per drug package insert
- Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
- Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2023

Vismodegib (Erivedge)

Specific Therapeutic Class: *Antineoplastic Agent, Hedgehog Pathway Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Basal Cell Carcinoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Basal Cell Carcinoma,** approve if:
  - Patient is 18 years of age or older
  - One of the following:
    - Patient has locally advanced disease that has recurred after surgery
    - Patient has locally advanced disease and is not a candidate for surgery or radiation
    - Patient has metastatic disease

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Vismodegib (Erivedge)

Last review/revision date: 10/2023

Voclosporin (Lupkynis)

Specific Therapeutic Class: *Calcineurin Inhibitor, Immunosuppressant Agent*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Lupus nephritis

Prescribing Restriction:

- Quantity Limit*: #180 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy
- Monitoring plan

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Lupus Nephritis**, approve if:
  - Patient is 18 years of age or older
  - The requested agent will be used as induction therapy for lupus nephritis
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least 1 of the following:
    - Cyclophosphamide + glucocorticoids
    - Mycophenolate + glucocorticoids
  - The requested agent will be used in combination with glucocorticoids and mycophenolate
  - The requested agent is not or will not be used in combination with cyclophosphamide
  - The patient has a baseline blood pressure less than or equal to 165/105mmHg and has not experienced a hypertensive crisis within the past 6 months
  - One of the following is true:
    - The prescribed dose is 23.7mg twice daily
    - The prescribed dose is less than or equal to 15.8mg twice daily if one of the following is true:
      a. eGFR is less than 60ml/min/1.73m2
      b. Patient is currently receiving moderate CYP 3A4 inhibitors

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- The patient is stable and continuing the medication

Voclosporin (Lupkynis)

- There is documented improvement from baseline or last review defined as positive changes in renal function, hypertension, and/or proteinuria
- There is documentation of ongoing need for therapy
- One of the following is true:
  - The prescribed dose is 23.7mg twice daily
  - The prescribed dose is less than or equal to 15.8mg twice daily if:
    - eGFR is less than 60ml/min/1.73m2
    - Patient is currently receiving moderate CYP 3A4 inhibitors

References: N/A

Last review/revision date: 10/2023

Vorinostat (Zolinza)

Specific Therapeutic Class: *Antineoplastic Agent, Histone Deacetylase (HDAC) Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Cutaneous T-cell lymphoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Cutaneous T-Cell Lymphoma**, approve if:
  - Patient is 18 years of age or older
  - Patient has progressive, persistent, or recurrent disease
  - Patient has previously received two systemic therapies

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 10/2022

Vosoritide (Voxzogo)

Specific Therapeutic Class: *C-type Natriuretic Peptide*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Achondroplasia

Prescribing Restriction:

- Quantity Limit*: #30 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Achondroplasia**, approve if:
  - Patient is 5 years of age or older
  - Patient has a diagnosis of achondroplasia confirmed by an FDA-approved genetic test
  - Documentation of recent annualized growth velocity (AGV)
  - Recent documentation showing that the patient has open epiphyses and a current AGV of ≥1.5 centimeters/year
  - Patient has not received previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids in the 6 months prior to request
  - Patient does not have planned or expected limb-lengthening surgery
  - If patient has had previous limb-lengthening surgery, the surgery occurred at least 18 months prior to the use of the requested agent

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Documentation of a clinically meaningful increase in AGV since last review
- Recent documentation showing that the patient has open epiphyses and a current AGV of ≥1.5 centimeters/year

References: N/A

Last review/revision date: 10/2022

Voxelotor (Oxbryta)

Specific Therapeutic Class: *Hemoglobin S Polymerization Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 12 months
- Continuation: 12 months

Diagnosis Considered for Coverage:

- Sickle cell disease

Prescribing Restriction:

- Quantity Limits: #90 per 30 days
- Prescriber restriction: Prescribed by or in consultation with a Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Sickle Cell Disease**, approve if:
  - Patient is 12 years of age or older
  - Patient has a baseline hemoglobin of 10.5mg/dL or less
  - Patient has experienced at least 1 vaso-occlusive crisis within the past 6 months
  - Patient is currently receiving hydroxyurea OR has a history of failure, intolerance, or contraindication to use hydroxyurea

II. Continuation of Therapy:

- There has been a reduction in vaso-occlusive crises
- There is documentation of an increase in hemoglobin from baseline

References: N/A

Last review/revision date: 10/2022

Zanubrutinib (Brukinsa)

Specific Therapeutic Class: *Antineoplastic Agent, Bruton Tyrosine Kinase Inhibitor, Tyrosine Kinase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: Indefinite
- Continuation: N/A

Diagnosis Considered for Coverage:

- Mantle cell lymphoma
- Marginal zone lymphoma
- Waldenström macroglobulinemia
- Chronic lymphocytic leukemia
- Small lymphocytic lymphoma
- Follicular lymphoma
- Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (evidence rating 2b or greater), Wolters Kluwer Lexi-Drugs, Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies)

Prescribing Restriction:

- Quantity Limit*:
  - Authorized quantity sufficient for a 30 day supply
  - Prescriber restriction: Prescriber must be an Oncologist or Hematologist

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Mantle Cell Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has received at least 1 prior chemotherapy regimen

- For the diagnosis of **Marginal Zone Lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has received at least 1 prior anti-CD20 based chemotherapy regimen

- For the diagnosis of **Waldenström Macroglobulinemia,** approve if:
  - Patient is 18 years of age or older

Zanubrutinib (Brukinsa)

- For the diagnosis of **Chronic lymphocytic leukemia,** approve if:
  - Patient is 18 years of age or older

- For the diagnosis of **small lymphocytic lymphoma,** approve if:
  - Patient is 18 years of age or older

- For the diagnosis of **Follicular lymphoma,** approve if:
  - Patient is 18 years of age or older
  - Patient has relapsed or refractory disease
  - Patient has received at least 2 prior systemic therapies

- For the diagnosis of **Off-Label Indications**, approve if:
  - Requested indication must be supported by NCCN category 2b or greater evidence rating. If the request is for a lower level of evidence rating, then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g., allergic reaction, contraindication)
  - Documentation provided of results of genetic testing where required per drug package insert
  - Documentation provided of results of all required laboratory values and patient specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert
  - Requested quantity does not exceed FDA approved or compendia supported dose

References: N/A

Last review/revision date: 6/2024

Zileuton (Zyflo)

Specific Therapeutic Class: *5-Lipoxygenase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Asthma

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Asthma**, approve if:
  - Patient is 12 years of age or older
  - Patient does not have active liver disease or transaminases greater than 3x the upper limit of normal
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use: montelukast tablet or chewable tablet AND zileuton ER

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 1/2023

Zileuton ER (Zyflo CR)

Specific Therapeutic Class: *5-Lipoxygenase Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 1 year
- Continuation: 1 year

Diagnosis Considered for Coverage:

- Asthma

Prescribing Restriction:

- Quantity Limit*: #120 per 30 days
- Prescriber restriction: N/A

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records
- Previous therapy

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Asthma**, approve if:
  - Patient is 12 years of age or older
  - Patient does not have active liver disease or transaminases greater than 3x the upper limit of normal
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use: montelukast tablet or chewable tablet

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- Medication is used for appropriate indication and at appropriate dose

References: N/A

Last review/revision date: 1/2023

Zilucoplan (Zilbrysq)

Therapeutic Category: *Complement C5 Inhibitor; Complement Inhibitor*
Formulary Status: Formulary, PA required

Coverage Duration

- Initial: 6 months
- Continuation: 6 months

Diagnosis Considered for Coverage:

- Myasthenia gravis

Prescribing Restrictions:

- Quantity Limit: #28 syringes per 28 days
  - Zilucoplan (Zilbrysq) 16.6mg/0.416ml: 11.65ml per 28days
  - Zilucoplan (Zilbrysq) 23mg/0.574ml: 16.08ml per 28 days
  - Zilucoplan (Zilbrysq) 32.4mg/0.81ml: 22.68ml per 28 days
- Prescriber restriction: Neurologist

Clinical Information Required for Review:

- Diagnosis and severity
- Medical records
- Dose

Coverage Criteria:

I. Initiation of Therapy:

- For diagnosis of **Myasthenia Gravis,** approve if:
  - Patient is 18 years of age or older
  - Patient has diagnosis of Myasthenia Gravis confirmed by an FDA-approved test
  - Patient is anti-acetylcholine receptor (AChR) antibody positive confirmed by a serological test
  - Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification greater than or equal to 2
  - Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score greater than or equal to 6
  - There is documentation of trial and failure with documented compliance, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use at least two of the following:
    - cholinesterase inhibitors
    - Steroids
    - NSISTs

II. Continuation of Therapy for EXISTING Members (Member previously met initiation of therapy criteria or documentation is provided with PA request that member is continuing the medication), approve if:

- Patient is stable and continuing the medication
- There is documentation of a sustained positive response to therapy from baseline confirmed by improvement in MGFA or MG-ADL score

References: N/A

Last review/revision date: 5/2024

Zuranolone (Zurzuvae)

Specific Therapeutic Class: *Antidepressant; Gamma-Aminobutyric Acid (GABA) A Receptor Positive Modulator*
Formulary Status: Formulary, PA required

Coverage Duration:

- Initial: 14 days
- Continuation: N/A

Diagnosis Considered for Coverage:

- Postpartum Depression

Prescribing Restriction:

- Quantity Limit*: #28 per 14 days (one treatment course total)
- Prescriber restriction: Prescribed by or in consultation with a Psychiatrist or OB/GYN

**Requests for quantities above indicated Quantity Limits will be reviewed on a case-by-case basis*

Clinical Information Required for Review:

- Diagnosis
- Medical records

Coverage Criteria:

I. Initiation of Therapy:

- For the diagnosis of **Postpartum Depression**, approve if:
  - Patient is 18 year of age or older
  - Patient has a diagnosis of severe postpartum depression confirmed by a PHQ-9 depression questionnaire score of 20 or more
  - Patient is less than or equal to 12 months postpartum
  - Patient is not currently pregnant
  - Patient does not have a past medical history of bipolar disorder, schizophrenia, or schizoaffective disorder

References: Spitzer RL, Kroenke K, Williams JB. Patient Health Questionnaire (PHQ). In: Handbook of Psychiatric Measures, Second Edition, Rush AJ Jr, First MB, Blacker D (Eds), American Psychiatric Publishing, Washington, DC 2008. p.58.

Last review/revision date: 2/2024