Health Choice Arizona

Medication Prior Authorization Criteria

October 1, 2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>ACCRUFER</td>
<td>ferric malitol</td>
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**CRITERIA FOR COVERAGE/NON-COVERAGE**

ACCRUFER (ferric malitol) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- 4 week trial and failure of, or contraindication to all formulary iron supplements (ferrous sulfate oral tablet 325 [65 Fe] mg)

AND

- Iron deficiency after the 4 weeks for treatment above as demonstrated by
  - Males: hemoglobin <11 g/dL or ferritin <8 μg/L
  - Females: hemoglobin <10 g/dL or ferritin <8 μg/L

Maximum quantity: two 30mg tablets twice daily

Approval duration: 24 weeks

Continuation criteria:

- Continued iron deficiency as demonstrated by
  - Males: hemoglobin <11 g/dL or ferritin <8 μg/L
  - Females: hemoglobin <10 g/dL or ferritin <8 μg/L

Re-approval duration: 12 weeks
**Actemra** is an interleukin-6 (IL-6) receptor antagonist indicated for the self-administered subcutaneous injection treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease Modifying Anti-Rheumatic Drugs (DMARDs).
- Adult patients with giant cell arteritis (GCA).
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.

Other indications such as systemic juvenile idiopathic arthritis (SJIA) and cytokine release syndrome (CRS) are FDA approved for administration of Actemra by intravenous infusion.

**Actemra** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) and one or more of the following:
      i. Clinical Disease Activity Index (CDAI) > 10.0
      ii. Disease Activity Score 28 (DAS) ≥ 3.2
      iii. Simplified Disease Activity Index (SDAI) > 11.0
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated:
      i. Methotrexate for ≥ 3 consecutive months
      ii. If documented intolerance or known contraindication to MTX, then one of the following disease-modifying antirheumatic agent for ≥ 3 consecutive months
         • Hydroxychloroquine
         • Sulfasalazine
         • Leflunomide
   f. Prescribed concomitantly with MTX or another agent if intolerance or contraindication to MTX;

   **Note:** Per 2015 ACR (American College of Rheumatology) Treatment Guidelines for rheumatoid arthritis biologic therapy should be used in combination with
methotrexate, when possible, due to superior efficacy of this combination over biologic monotherapy.

g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).

h. Recent lab documentation submitted of hepatic function, absolute neutrophil count (ANC), and platelet count.

i. Requested dose and dosing interval is consistent with the FDA labeled recommended dosing for Actemra and with the current weight (within 30 days) of the member.

j. Documentation Actemra will be administered by subcutaneous self-injection by the member.

2. Giant Cell Arteritis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of giant cell arteritis.
   e. Documented trial and failure of, or contraindication to or intolerance of, at least one of the following:
      i. Glucocorticoids (e.g., prednisone, methylprednisolone)
      ii. Methotrexate
   f. Recent lab documentation submitted of hepatic function, absolute neutrophil count (ANC), and platelet count.
   g. Documentation Actemra will be administered by subcutaneous self-injection by the member.

3. Polyarticular juvenile idiopathic arthritis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age of member is ≥ 2 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of moderate to severe arthritis with at least five swollen joints and at least three joints with limitation of motion.
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated
      i. Methotrexate for at least 30 days
      ii. Oral NSAID for at least 30 days
      iii. Oral corticosteroid for at least 14 days
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
   g. Requested dose and dosing interval is consistent with the FDA labeled recommended dosing for Actemra and with the current weight (within 30 days) of the member.
   h. Recent lab documentation submitted of hepatic function, absolute neutrophil count (ANC), and platelet count.
   i. Documentation Actemra will be administered by subcutaneous self-injection by the member.
Approval Length: Three months initially then up to 12 months thereafter based on clinical response.

Quantity Limits: Up to four prefilled syringes per 30 days based on diagnosis.

Continuation Criteria:

Rheumatoid arthritis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters by a result of at least one of the following disease activity measurements listed below.

- Clinical Disease Activity Index (CDAI) < 10.0
- Disease Activity Score 28 (DAS) ≤ 3.2
- Simplified Disease Activity Index (SDAI) < 11.0

Giant cell arteritis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters including both of the following:

- Normalization of erythrocyte sedimentation rate to < 30 mm/hour for women and < 23 mm/hour for men.
- Normalization of C-reactive protein to < 1 mg/dL.

Polyarticular juvenile idiopathic arthritis – Documentation submitted supporting member has achieved and is maintaining a 30% improvement in number of joints with active arthritis and the number of joints with limitation of movement.

For all diagnoses: If member is transitioning to the subcutaneous injection formulation from intravenous infusion then all initial pharmacy benefit criteria must be met in full.

Exclusions:

1. Concomitant use with other biologic DMARD medications (oral and injectable).
2. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
3. The following is a list of acceptable contraindications for the use of methotrexate:

   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:


Criteria effective: 10/01/2018; Last reviewed April 2019
<table>
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<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>ACTIMMUNE</td>
<td>Interferon gamma-1b</td>
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**CRITERIA FOR COVERAGE/NONCOVERAGE**

**ACTIMMUNE/Interferon gamma-1b** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member must meet the following criteria for initial authorization:

1. The member must be clinically diagnosed with one of the following conditions:
   a. Chronic Granulomatous Disease (CGD): Actimmune is being used to reduce the frequency and severity of serious infections associated with CGD.
   b. Malignant osteopetrosis (severe): Actimmune is being used to delay time to disease progression.

Criteria for continuation:

1. For Chronic Granulomatous Disease: documentation has been provided that the member has had a positive response to treatment defined as a reduction in frequency and severity of serious infections.
2. For Malignant osteopetrosis: documentation has been provided that the member’s disease progression has been slowed.

Approval will be granted for 6 months (if no improvement within 6 months discontinue treatment)

**References**


Criteria last updated: 2/2019
### CRITERIA FOR COVERAGE/NONCOVERAGE

**ADHD Medications** will be considered for initial coverage under the pharmacy benefit program when the following criteria are met:

1. The requesting clinician has documented that the child has a diagnosis of ADHD.
2. Psychosocial issues and non-medical interventions are being addressed by the clinical team.
3. Documentation of psychosocial evaluation occurring before request for ADHD medications.
   a. Documentation provided includes date of evaluation and name of clinician conducting assessment.
4. Documentation of non-medication alternatives that have been attempted before request for ADHD medications.
   a. Documentation provided includes interventions tried, date and duration of trial and why interventions were unsuccessful.
5. If dose is greater than FDA approved maximum daily dose, provide details and supporting documentation.
6. Prescriber attests to monitoring child in accordance with the ADHS/DBHS Clinical Practice Protocol on Psychiatric Best Practice Guidelines for Children: Birth to Five Years of Age.
7. Prescribed by or in consultation with a child psychiatrist.

**Coverage is Not Authorized for:**

1. Indications other than ADHD.
2. Doses greater than FDA recommended maximum daily dosage unless accompanied with supporting documentation.

**Renewal Criteria:**

Documentation of positive response to therapy

**Initial approval:** 6 months

**Renewal:** 12 months

References:

1. ADHS/DBHS: Provider Manual Section 3.15: Psychotropic Medication: Prescribing and Monitoring
2. Manufacturer Product Information

Criteria last updated: March 2019
Requests for formulary drugs when prior authorization criteria is unavailable will be considered for coverage under the pharmacy benefit program when all of following criteria are met:

1. Drug (and prescription) must be prescribed by a Health Choice contracted provider.

2. The requested medication and the diagnosis must meet either a, b, or c listed below.

   a. Requested medication and the diagnosis must meet the FDA indication in full.

      In full defined as indication, drug strength, directions, dosing modifications, warnings, contraindications, any black box warnings, and any other pertinent clinical information as per the prescribing information. Documentation is required and all of the below must be met:

      i. Recent chart notes that include the treatment plan with the requested formulary medication.

      ii. Lab work pertaining to drug as indicated per the FDA prescribing information.

         Example: Hepatic, renal function, or other labs that would affect the approvable quantity if impairment exists.

   b. Compendia. If the FDA indication is not met in full then the request is considered off-label and must meet one of the following compendia in full.

      i. American Hospital Formulary Service (AHFS) Compendium.

      ii. Micromedex/DrugDex Compendium with a Class I, IIa, or IIb rating.

      iii. Elsevier Gold Standard’s Clinical Pharmacology Compendium with a strong recommendation.


      v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) Category of 1, 2A, or 2B.
c. **Evidence.** If the FDA indication or compendia is not met then **two** published, double-blinded, peer-reviewed, controlled, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug and/or quantity with the diagnosis can be submitted for review.

The clinical trials must be consistent with the drug requested in terms of the dosing, the patient type in all aspects, and the disease to be treated being requested. The conclusion by the trial authors must include it is considered safe and effective for the requested use.

**Clinical Trial Phases:**

- **Preclinical research:** A trial done in a lab and not tested in animals or humans.
- **Phase 0:** The first clinical trials to be done among people. In these trials a very small dose of a drug is given to about 10 to 15 people.
- **Phase I:** An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects.
- **Phase II:** An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete.
- **Phase III:** Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way.
- **Phase IV:** After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment’s risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials.

**Approval length:** Up to 12 months unless the medication is clinically indicated for a shorter duration of use.

**Continuation criteria:**

1. Chart notes documenting a positive response to therapy and no intolerable side effects. Labs may be required to support response to therapy if indicated per the prescribing information.
References:


4. Facts & Comparisons Answers. Available at: [http://online.factsandcomparisons.com].

5. Micromedex/DRUGDEX. Available at: [www.microdextrasolutions.com].


Criteria last reviewed and updated: 6/2019
Ajovy is an all human monoclonal antibodies that inhibits the calcitonin gene-related peptide (CGRP) receptor and are indicated for the preventive treatment of migraines in adults.

Ajovy is available for administration in two dosing options, either as 225 mg (one injection) one time a month or 675 mg (three injections at one time) every 3 months.

**Ajovy** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by or in consultation with a neurologist or a pain management specialist.
2. The member is ≥ 18 years of age.
3. Documented trial of at least 60 days and failure to formulary CGRP (Aimovig, Emgality)
4. Documentation submitted that meets one of the following:
   a. A diagnosis of **episodic migraines** and all of the following must be met:
      1. Documentation member has at least 4 to 14 migraine days per month, but no more than 14 headache days per month.
      2. Trial of at least 2 months and documented failure, contraindication, or intolerance to all of the following prophylactic therapies listed from each of the drug classes below:
         - Antidepressants (amitriptyline, venlafaxine)
         - Antiepileptics (divalproex, topiramate)
         - Beta-blockers (atenolol, propranolol, nadolol, timolol, metoprolol)
   b. A diagnosis of **chronic migraines** and all of the following must be met:
      1. Documentation member has been evaluated for medication overuse headache (MOH) and if MOH is diagnosed then documentation has been submitted the member has successfully tapered off the offending medication.
         Note: The use of acute therapy more frequently than 10 days per month is associated with the development of medication overuse headaches and chronic daily headaches. Opioids and barbiturates are associated with the highest risk for medication overuse headaches, although frequent use of NSAIDS and triptans can also lead to chronic migraines and medication overuse headaches.
      2. Documentation member has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months.
      3. Trial of at least 2 months and documented failure, contraindication, or intolerance to one drug from each of the following prophylactic drug classes listed below:
         - Antidepressants (amitriptyline, venlafaxine)
Antiepileptics (divalproex, topiramate)
Beta-blockers (atenolol, propranolol, nadolol, timolol, metoprolol)
Botox (onabotulinumtoxinA) – verified by medical claim history

Approval Length: Three months

Quantity Limits:

**Ajovy** - One injection of 225 mg one time a month or three injections (675 mg) every 3 months.

Continuation Criteria:
1. Documentation submitted member has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity compared to baseline. The number of migraine days per month must be documented and submitted.
2. Per prescription claims history the use of acute migraine medications (e.g., NSAIDs, triptans, opiates and other migraine medications) has decreased while on therapy.
3. Documentation that member continues to be monitored for Medication Overuse Headache (MOH) and offending medications, if applicable.

Exclusions:
1. *Aimovig, Ajovy, and Emgality* will not be used in combination with each other.
2. *Aimovig, Ajovy, and Emgality* will not be used in combination with Botox (onabotulinumtoxinA).

References:

Criteria last reviewed: September 2019
### Brand Name | Generic Name
---|---
AMITIZA | lubiprostone

### CRITERIA FOR COVERAGE/NON-COVERAGE

**Amitiza** is a chloride channel activator indicated for the treatment of chronic idiopathic constipation in adults, the treatment of irritable bowel syndrome (IBS) with constipation in women ≥ 18 years old and for the treatment of opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation. The effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids such as methadone has not been established.

**Amitiza** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses, with symptoms occurring for at least 6 months:
   a. For the treatment of chronic idiopathic constipation in adults, when prescribed by or in consultation with a specialist in gastroenterology, and other possible causative conditions have been appropriately treated first.
   b. For the treatment of IBS with constipation with pain and discomfort in women ≥ 18, when prescribed by, or in consultation with a specialist in gastroenterology, and IBS has first been appropriately treated.
   c. For the treatment of opioid-induced constipation in adults with chronic non-cancer pain, for members currently taking an opioid, verified by prescription claims history.

2. Trial and failure of three of the following listed below. Documentation must include dates of trial and failure in the chart notes and supported by prescription claims history. Trial must consist of a minimum of 30 days.
   a. An increase in dietary fiber by food and by fiber supplements (Metamucil).
   b. One saline laxative, such as milk of magnesia or magnesium citrate.
   c. Lactulose.
   d. Polyethylene glycol (Miralax).
   e. One stimulant laxative, such as sennosides (Ex-lax, Senokot), bisacodyl (Dulcolax) or cascara sagrada, glycerin, or bisacodyl suppository.
Approval length: 6 months initially then 12 months thereafter.

Continuation criteria:

1. Consistent prescription claim history, and non-adherence addressed, if observed
2. Documentation member is receiving a positive clinical response defined as an increase in SBMs per week.

References:

Criteria reviewed: 02/2019
Criteria revised: 02/2019
Applies to: Citalopram, escitalopram, fluoxetine caps & soln, fluvoxamine, paroxetine, sertraline, nefazodone, trazodone, desvenlafaxine, duloxetine, venlafaxine caps & tabs and all formulary tricyclic antidepressants

Antidepressants will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The requesting clinician has documented the child has a diagnosis of one of the following as per current DSM-IV criteria and is deemed to be of sufficient severity to warrant medication use:
   - Major depressive disorder (MDD).
   - Obsessive compulsive disorder (OCD)
   - Anxiety disorder
2. Psychosocial issues and non-medical interventions are being addressed by the clinical team.
   - Documentation provided includes interventions tried, date and duration of trial, and why interventions were unsuccessful.
3. Documentation of psychotherapeutic intervention (e.g., Dyadic therapy) occurring for at least 6 to 9 months before requesting antidepressant therapy.
   - Documentation provided includes interventions tried, date and duration of trial, and why interventions were unsuccessful.
4. Prescribed by, or in consultation with, a child psychiatrist.
5. Member will continue with psychosocial treatment while on antidepressant medication.
6. Documentation must include information on the expected outcomes and an evaluation of the potential adverse events.

Approval Length: Authorization for continued use shall be reviewed at least every 3 months to confirm medical necessity and lack of contraindications to continued therapy. Maximum approval length of six to nine months total, discontinuation and gradual downward titration should have occurred starting at 6 months of any effective medication therapy.

Exclusions:
1. Indications other than MDD, OCD, and anxiety.
2. The use of antidepressants without psychosocial treatment.

References:
Criteria revised March 2018; Reviewed March 2019
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<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>ANZEMET</td>
<td>dolasetron</td>
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**CRITERIA FOR COVERAGE/NON-COVERAGE**

*ANZEMET / dolasetron* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member is receiving radiation therapy or moderate to highly emetogenic chemotherapy AND
2. Member had an inadequate response, intolerance, or contraindication to a trial of ondansetron (generic Zofran) and granisetron.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References

Criteria last reviewed: February 2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>AVACLYR</td>
<td>acyclovir ophthalmic ointment</td>
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**CRITERIA FOR COVERAGE/NON-COVERAGE**

AVACLYR (acyclovir ophthalmic ointment) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- documented herpes simplex virus (HSV-1 or HSV-2)  
  
  AND

- documented visualization of acute herpetic keratitis (i.e. dendritic ulcers) upon exam

Maximum quantity: one 10mL tube

**Approval duration: 1 month**

Continuation criteria:

- documentation of persistence of herpetic keratitis (i.e. dendritic ulcers) upon exam

Reapproval duration: 1 month
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<tr>
<th>Brand Name</th>
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<tr>
<td>AZOPT</td>
<td>brinzolamide</td>
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CRITERIA FOR COVERAGE/NON-COVERAGE

AZOPT/brinzolamide will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The member has one of the following diagnoses:
  - ocular hypertension or open-angle glaucoma

AND

- Member had trial and failure of or has contraindication to doxolamide (generic Trusopt) or Dorzolamide/timolol (generic Cosopt).

Approval duration: 12 months.

Member must meet following for reauthorization:

- Member is receiving positive clinical response to therapy.

Approval duration: 12 months.

References


Criteria last updated: March 2019
Belsomra is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Belsomra will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia (trouble initiating or maintaining sleep for at least three nights per week for at least three months).
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days and failure of each of the following at maximum therapeutic doses:
   a. Zolpidem 10mg
   b. Temazepam 30mg
   c. Eszopiclone 3mg

Exclusions for coverage:

1. Documented diagnosis of narcolepsy.
2. Severe hepatic impairment defined as Child-Pugh Class C.
3. Concomitant use with other insomnia medications.
4. Concomitant use with modafinil or armodafinil.

Approvable quantity:

1. Quantities greater than #30 per 30 days will not be approved.

Continuation criteria:

Documentation member has been reevaluated for continued necessity and is receiving a positive clinical response evidenced by a decrease in nights per week with sleep maintenance difficulties.

Initial/continuation approval length: 12 months.

References:


Criteria last updated 6/2019
<table>
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<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>BEVESPI AEROSPHERE</td>
<td>glycopyrrolate/formoterol</td>
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<tr>
<td>STIOLTO RESPIMAT</td>
<td>tiotropium/olodaterol</td>
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**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Bevespi Aerosphere** is a combination of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta$_2$-adrenergic agonist (LABA) and is indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). The recommended dose is two inhalations twice a day.

**Stioltto Respimat** is a combination of tiotropium, a LAMA, and olodaterol, a LABA, and is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD. The recommended dose is two inhalations once a day at the same time of day. It is not to be used more than two inhalations every 24 hours.

The above medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of COPD.

**Approval Length:** 12 months  
**Quantity Limits:** One inhaler per 30 days  
**Continuation Criteria:**
1. Documentation submitted member is having a positive response to therapy evidenced by an increase in FEV1 from baseline.

**References:**

Criteria last reviewed March 2019
<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Reference Brand Name</th>
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<tbody>
<tr>
<td>Celecoxib</td>
<td>CELEBREX</td>
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**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Celecoxib** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member must meet one of the following criteria for initial authorization:

- Member is > 65 years of age
- Member has a trial and failure of an intolerance to TWO formulary Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) (e.g. ibuprofen, diclofenac sodium, naproxen, etodolac, nabumetone) Member has been on following drug therapy in previous 90 days:
  - i. Anticoagulants/antiplatelet agents (e.g., warfarin, Xarelto, Pradaxa, clopidogrel, Eliquis)
  - ii. Antiulcer agents (i.e. proton-pump inhibitors (PPIs) (e.g., pantoprazole, omeprazole, lansoprazole), histamine H2 receptor antagonists (H2RAs) (e.g. ranitidine, famotidine))
  - iii. Chronic use of oral corticosteroids (i.e. prednisone)
  - iv. Use of methotrexate
- Patient has a history of peptic ulcer disease (PUD) or history of gastrointestinal (GI) bleed

**Approval duration: 12 months**

Member must meet following for reauthorization:

- Member is receiving positive response to therapy.

Approval duration: 12 months.

References

Criteria last reviewed and updated: January 2019
Prior Authorization Required

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>AIMOVIG</td>
<td>erenumab-aooe</td>
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<tr>
<td>EMGALITY</td>
<td>galcanezumab-gnlm</td>
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**CRITERIA FOR COVERAGE/NON-COVERAGE**

Aimovig and Emgality are all human monoclonal antibodies that inhibits the calcitonin gene-related peptide (CGRP) receptor and are indicated for the preventive treatment of migraines in adults.

Aimovig is available as a subcutaneous injection self-administered monthly at 70 mg. Some patients may benefit from use of 140 mg once monthly which is administered as two consecutive injections of 70 mg each.

Emgality is administered as 240 mg (two consecutive injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg when used for the preventative treatment of migraine.

Emgality is administered as 300mg (three consecutive injections of 100mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.

*Aimovig or Emgality* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by or in consultation with a neurologist or a pain management specialist.
2. The member is $\geq 18$ years of age.
3. Documentation submitted that meets **one** of the following:
   a. A diagnosis of **episodic migraines** and all of the following must be met:
      3. Documentation member has at least 4 to 14 migraine days per month, but no more than 14 headache days per month.
      4. Prescriber attests that the patient has experienced a trial of at least 2 months and documented failure, contraindication, or intolerance to two prophylactic therapies from the drug classes below:
         - Antidepressants (amitriptyline, venlafaxine)
         - Antiepileptics (divalproex, topiramate)
         - Beta-blockers (atenolol, propranolol, nadolol, timolol, metoprolol)
   b. A diagnosis of **chronic migraines** and all of the following must be met:
2. Documentation member has been evaluated for medication overuse headache (MOH) and if MOH is diagnosed then documentation has been submitted the member has successfully tapered off the offending medication.

   **Note:** *The use of acute therapy more frequently than 10 days per month is associated with the development of medication overuse headaches and chronic daily headaches. Opioids and barbiturates are associated with the highest risk for medication overuse headaches, although frequent use of NSAIDS and triptans can also lead to chronic migraines and medication overuse headaches.*

2. Documentation member has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months.

3. Prescriber attests that the patient has experienced a trial of at least 2 months and documented failure, contraindication, or intolerance to two prophylactic therapies from the drug classes below:
   - Antidepressants (amitriptyline, venlafaxine)
   - Antiepileptics (divalproex, topiramate)
   - Beta-blockers (atenolol, propranolol, nadolol, timolol, metoprolol)

   **c.** A diagnosis of [episodic cluster headache](EMGALITY ONLY) and all of the following must be met:

   1. Documentation member has experienced:
      - At least 5 attacks which are characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes when untreated [during part (but less than half) of the time-course of cluster headache, attacks may be less severe and/or of shorter or longer duration];
        - Attacks are characterized by sense of restlessness or agitation;
        - Attacks are associated with at least one of the following symptoms/signs ipsilateral to the headache: Conjunctival injection and/or lacrimation, nasal congestion and/or rhinorrhea, eyelid edema, forehead and facial sweating, miosis and/or ptosis;
        - Attacks have a frequency between one every other day and eight per day [during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent];
        - Attacks occur in bouts (cluster periods);
      - At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of three months or more

2. Prescriber attests that the patient has experienced a trial of at least 2 months and documented failure, contraindication, or intolerance to Verapamil and Topiramate

**Approval Length:** Three months
Quantity Limits:

**Aimovig** - The approvable initial quantity is one 70 mg injection once a month. The use of two 70 mg (140 mg) injections per month will require documentation of failure of 70 mg once a month after a 90 day trial with complete adherence per prescription claims. Failure is defined as not meeting the continuation criteria of a positive response to therapy demonstrated by a reduction in headache frequency and/or intensity compared to baseline.

**Emgality** - Two initial consecutive injections of 120 mg each once as a loading dose, followed by one injection one time a month of 120 mg.

Continuation Criteria:

1. Prescriber attestation member has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity compared to baseline and decreased use of acute migraine medications (NSAIDs, triptans, opiates).

Exclusions:

1. Aimovig and Emgality will not be used in combination with each other or with Ajovy
2. Aimovig and Emgality not be used in combination with Botox (onabotulinumtoxinA).

References:


Criteria last updated 6/2019
Cimzia is a self-administered subcutaneous injection of a tumor necrosis factor (TNF) blocker indicated for:

- Treatment of adults with moderately to severely active rheumatoid arthritis
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with active ankylosing spondylitis
- Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Reducing signs and symptoms of Crohn’s disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy

Cimzia will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) and one or more of the following:
      iv. Clinical Disease Activity Index (CDAI) > 10.0
      v. Disease Activity Score 28 (DAS) ≥ 3.2
      vi. Simplified Disease Activity Index (SDAI) > 11.0
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated:
      i. Methotrexate for ≥ 3 consecutive months
      ii. If documented intolerance or known contraindication to MTX, then one of the following disease-modifying antirheumatic agent for ≥ 3 consecutive months
         - Hydroxychloroquine
         - Sulfasalazine
         - Leflunomide
   f. Prescribed concomitantly with MTX or another agent if intolerance or contraindication to MTX;

   **Note:** Per 2015 ACR (American College of Rheumatology) Treatment Guidelines for Rheumatoid Arthritis biologic therapy should be used in combination with methotrexate, when possible, due to superior efficacy of this combination over biologic monotherapy.
g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
h. Documentation submitted supporting Cimzia will be self-administered by the member at a maintenance dose of 400 mg every 4 weeks or 200 mg every 2 weeks after an initial induction dose of 400 mg at Week 0, Week 2, and Week 4.

2. Psoriatic arthritis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe psoriatic arthritis and one or more of the following:
      vii. Clinical Disease Activity Index (CDAI) > 10.0
      viii. Disease Activity Score 28 (DAS) ≥ 3.2
      ix. Simplified Disease Activity Index (SDAI) > 11.0
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated:
      i. Methotrexate for ≥ 3 consecutive months
      ii. If documented intolerance or known contraindication to MTX, then one of the following disease-modifying antirheumatic agent for ≥ 3 consecutive months:
         - Hydroxychloroquine
         - Sulfasalazine
         - Leflunomide
   f. Prescribed concomitantly with MTX or another agent if intolerance or contraindication to MTX.

   Note: Per 2015 ACR Treatment Guidelines for rheumatoid arthritis biologic therapy should be used in combination with methotrexate, when possible, due to superior efficacy of this combination over biologic monotherapy.

   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
   h. Documentation submitted supporting Cimzia will be self-administered by the member at a maintenance dose of 400 mg every 4 weeks or 200 mg every 2 weeks after an initial induction dose of 400 mg at Week 0, Week 2, and Week 4.

3. Ankylosing Spondylitis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Documentation submitted member has no latent or active tuberculosis infection.
   c. Age ≥ 18 years old.
   d. Documented diagnosis of ankylosing spondylitis.
   e. Trial and failure, unless intolerant or contraindication, per documentation submitted and per prescription claims history of the following:
      i. Two or more prescription required non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, and for greater than 30 days.
Formulary NSAIDs include: ibuprofen, naproxen, naproxen DR, piroxicam, diclofenac, meloxicam, nabumetone, oxaprozin, indomethacin, indomethacin ER, flurbiprofen, fenoprofen, and etodolac.

Note: Oral NSAIDs are recommended as the first-line drug for ankylosing spondylitis per the 2016 ASAS/EULAR guidelines.

f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira and Enbrel.

g. Documentation submitted supporting Cimzia will be self-administered by the member at a maintenance dose of 400 mg every 4 weeks or 200 mg every 2 weeks after an initial induction dose of 400 mg at Week 0, Week 2, and Week 4.

3. Plaque Psoriasis (Adult)
   a. Prescribed by or in consultation with a dermatologist or rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
      
      Note: An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.

   e. Documented trial of phototherapy either in-office or in-home use unless a supported contraindication for use is submitted.

   f. Documentation member has failed topical therapy for a trial of at least 90 days and includes three of the following verified by prescription claims history:
      i. Calcipotriene (generic for Dovonex) topical preparations
      ii. Medium-to-high potency corticosteroids
         
         Note: For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
      iii. Tazarac topical gel 0.05%
      iv. Tacrolimus 0.1% (prior authorization required) ointment
      v. Coal tar preparations such as coal tar shampoo

   g. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
      i. Methotrexate oral tablets
      ii. Cyclosporine oral capsules
      iii. Acitretin capsules (generic for Soriatane) – prior authorization required

   h. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).

   i. Documentation submitted supporting Cimzia will be self-administered by the member at a maintenance dose of up to 400 mg (two 200 mg injections) every other week.
4. **Crohn’s Disease**
   a. Prescribed by or in consultation with a gastroenterologist.
   b. Age ≥ 18 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderately to severely active Crohn’s disease.
   e. Member has failed two of the following therapies verified per prescription claims history, unless supported intolerance or contraindication submitted, for ≥ 3 consecutive months:
      i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
      ii. An oral corticosteroid or controlled release budesonide
      iii. A thiopurine such as azathioprine
      iv. Methotrexate
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of **Humira** (adalimumab).
   g. Documentation submitted supporting Cimzia will be self-administered by the member at a maintenance dose of 400 mg and a dosing interval of no less than every 4 weeks after the initial induction dosing of 400 mg at Week 0, Week 2, and at Week 4.

**Approval Length:** Three months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits:** Consistent with FDA labeled dosing for induction and maintenance therapy based on diagnosis and current weight if applicable.

**Continuation Criteria:**

*Rheumatoid arthritis and Psoriatic arthritis* – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters by a result of at least one of the following disease activity measurements listed below.

- Clinical Disease Activity Index (CDAI) < 10.0
- Disease Activity Score 28 (DAS) ≤ 3.2
- Simplified Disease Activity Index (SDAI) < 11.0

*Ankylosing spondylitis* – Documentation submitted supporting decrease in at least one of the following:

1. Back pain
2. Serum C-reactive protein

*Psoriasis (adult and adolescent)* – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters based on decreased total percent BSA affected.

*Crohn’s disease* – One of the following must be met:

1. Documentation submitted supporting symptomatic remission has occurred **OR** Crohn’s disease activity score (CDAI) < 150.
2. Documentation submitted supporting decrease in overall symptoms from pre-treatment baseline of all or a majority of symptoms (weight loss, abdominal pain or tenderness, intermittent nausea or vomiting, or significant anemia) **OR** a CDAI score < 220.
Exclusions:
1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
2. For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
3. Concomitant use with other biologic medications (oral and injectable).
4. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:

Criteria effective: 10/01/2018; Last reviewed April 2019
Cinacalcet will be considered for coverage when the following criteria are met:

1. Member must be clinically diagnosed with one of the following conditions and meet individual criteria if stated:
   A. Secondary hyperparathyroidism due to chronic kidney disease who meet (a) and (b) below:
      a. Member is on dialysis
      b. Documented trial and failure, intolerance, or contraindication to both of the following:
         i. A phosphate binder (e.g. calcium acetate, Fosrenol/lanthanum, Renvela, Renagel)
         ii. A vitamin D analog (e.g. calcitriol, doxercalciferol, Zemplar)
   B. Hypercalcemia due to parathyroid carcinoma
   C. Severe hypercalcemia (calcium > 12.5mg/dL) with primary hyperparathyroidism and unable to undergo parathyroidectomy

2. iPTH is ≥300 pg/mL (biPTH > 160) and calcium is ≥8.4 mg/dL in order to initiate therapy

Approval length: Three months initially. If member meets guidelines for continuation, approval can be extended to 12 months.

Continuation Criteria:
1. The member has experienced a reduction in serum calcium from baseline
2. The member does not have hypocalcemia

References

Criteria last reviewed: 6/2019
**Nonformulary**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CINRYZE</td>
<td>C1 esterase inhibitor [human]</td>
</tr>
<tr>
<td>HAEGARDA</td>
<td>C1 esterase inhibitor [human]</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

*Cinryze* is a C1 esterase inhibitor indicated for routine prophylaxis against angioedema attacks in adolescent (6yo and up) and adult patients with Hereditary Angioedema (HAE). Recommended dosing is 1,000 units every 3 to 4 days (ages 12 and up). Recommended dosing for ages (6 – 11) = 500 Units Intravenous every 3 or 4 days.

*Haegarda* is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent HAE attacks in adolescent and adult patients. Recommended dosing is 60 units per kg of body weight every 3 to 4 days.

Both products are considered self-administered medications. Training by a healthcare provider is required before the self-administration of intravenously infused Cinryze. Haegarda is administered as a subcutaneous injection after reconstitution.

The above medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Documented diagnosis of Type I or Type II hereditary angioedema and the request is prescribed by an immunologist and/or allergist.
2. Clinical laboratory documentation of serum C4 and C1-INH (antigenic or functional level) that are below the limits of the laboratory’s normal reference range.
3. The member’s history of HAE attacks is consistent with at least one of the following criteria:
   a. One or more abdominal or respiratory attacks per month
   b. History of recurrent laryngeal attacks
   c. Requires emergency medical care three or more times per year
4. Documentation by chart notes, and by prescription claim history if applicable, that HAE triggers have been identified and are being appropriately treated and/or avoided.
5. The member has had an insufficient response or contraindication to one medication* in both of the following classes of medication:
   a. 17α – alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
   b. Antifibrinolytic agents (e.g. aminocaproic acid, tranexamic acid)
   *One or more of these products may require prior authorization approval prior to use.
6. An adequate trial of at least 30 days with an “on-demand” HAE therapy product such as Firazyr (icatibant) did not provide satisfactory improvement in severity and frequency of HAE attacks.

7. Approval of Haegarda requires the prescriber has completed and submitted an FDA MedWatch Adverse Event Reporting Form regarding the therapeutic failure of or allergic reaction to Cinryze for their patient. The prescriber must provide a copy of the completed MedWatch form. Authorization of Haegarda will not be considered unless the form is completed and submitted to the FDA.

   Information regarding MedWatch, the FDA Safety Information and Adverse Event Reporting Program can be found at: [www.fda.gov/Safety/MedWatch](http://www.fda.gov/Safety/MedWatch)

   The MedWatch form for healthcare professionals can be found at: [www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)

8. Documentation supporting member has been adequately trained by the prescribing specialist to self-administer the medication and to store the medication appropriately as per the ‘Dosage and Administration’ section in the respective FDA approved prescribing information.

   **Approval Length:** Six months.

   **Quantity Limits:**
   
   *Cinryze* – Up to 20 vials (500 units per vial) per 30 days. Requests for quantities greater than 20 vials per 30 days will be reviewed case by case and require medical director review. Up to a maximum of 2,500 units every 3 to 4 days and not exceeding 100 units/kg may be approved based on individual patient response.

   *Haegarda* – An appropriate quantity based on the current weight submitted with the initial prior authorization request and with renewals.

   **Continuation Criteria:**
   
   1. Documentation by chart notes, and by prescription claim history if applicable, that HAE triggers have been identified and are being appropriately treated and/or avoided.

   2. Documentation submitted supporting significant improvement in severity and duration of attacks has been achieved and sustained compared to baseline. Baseline defined as before the initiation of treatment with Cinryze or Haegarda.

   **Exclusions:**
   
   1. Dual therapy with other C1-esterase inhibitors for the prevention of angioedema attacks. The use of Cinryze and Haegarda simultaneously is not supported by evidence or guidelines.

   **References:**
   


Criteria created March 2018; last reviewed April 2019
### CRITERIA FOR COVERAGE/NONCOVERAGE

**Clobazam** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has an FDA approved diagnosis of seizures associated with Lennox-Gastaut Syndrome.

2. Member is 2 years of age or older.

3. Prescribed by, or in consultation with a Neurologist.

4. Member has tried at least two seizure medications.

5. Member will be on a seizure medication while on Onfi.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

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**References**

Criteria last updated: September 2019
CRITERIA FOR COVERAGE/NONCOVERAGE

**Compounds** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by a valid provider for the treatment of an FDA-approved indication, or clinically accepted indication supported by medical literature and is medically necessary.

2. The route of administration or method of delivery is supported by medical literature.

3. Member is unable to use a commercially available product due to one of the following:
   a. No comparable commercially available product (i.e. dosage form or route of administration).
   b. Market withdrawal due to economic concerns, not safety concerns.
   c. Manufacturer shortage of commercial product with no estimated availability date.
   d. Member has a hypersensitivity to any of the components (i.e. dyes, preservatives, fragrances, etc.).
   e. Member has a physical disability that would prevent use of a commercially available product (e.g. inability to swallow, etc.).
   f. There is a documented contraindication to any of the components in the commercially available product.

4. All ingredients are supported by medical literature for the stability and efficacy of the compound. The use of high cost ingredients where less costly alternatives are available must be supported by documentation and stability and efficacy are supported by medical literature.

5. Prior authorization requirements for specific active ingredients have been met, if applicable

**Plan will not approve coverage of prescription compounds in the following instances:**

1. Compound ingredients exceed FDA approved maximum dosing
2. Compound contains only over-the-counter ingredients
3. Compound contains only non-active ingredients
4. Compound contains non-covered bulk chemical products
5. Compound contains Plan excluded product(s)
6. Compound is used for the treatment of Plan excluded indications
7. Supporting documentation is not provided (i.e. chart notes, clinical trials, etc.)

Approval will be granted for 12 months unless shorter duration requested by prescriber.

Criteria last updated 5/2019
Concomitant Antidepressant Therapy

Applies to concomitant use of:
1. Two SSRIs
2. SSRI in combination with an SNRI
3. Two SNRIs
4. Two Tricyclics (TCAs)
5. TCA with SSRI/SNRI

CRITERIA FOR COVERAGE/NONCOVERAGE

Concomitant Antidepressants will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Diagnosis of Treatment Resistant Depression or Obsessive Compulsive Disorder (trial and failure with clomipramine with fluvoxamine). For other uses, please submit the required prior authorization and supporting documentation.
2. Approval will be granted when a member over 18 years of age is cross tapering while transitioning from one medication to another over the course of 60 days.*
3. Evidence of adequate trial and failure of at least three (3) individual antidepressant agents listed on the AHCCCS Behavioral Health Drug List from at least two (2) different therapeutic classes, for 4-6 weeks at maximum tolerated doses. Failure is due to one of the following:
   a. An inadequate response at maximum tolerated doses
   b. Adverse reaction(s)
   c. Breakthrough symptoms
4. Prescriber must provide supporting documentation of all of the following:
   a. Adherence to the treatment regimen is not a contributing factor to the inadequate response to the medication trials.
   b. Appropriate clinical monitoring has been completed for TCAs (tricyclic antidepressants), which includes but is not limited to, TCA (tricyclic antidepressant) levels and/or an ECG (electrocardiogram) at baseline and follow-up.
   c. Appropriate clinical monitoring of target symptoms, adverse reactions including but not limited to signs and symptoms of serotonin syndrome, and adherence to treatment, suicide risk, heart rate, blood pressure and weight has been completed.
   d. Provider should provide attestation that coordination of care is occurring if medication is prescribed by more than one provider.

*Cross tapers may be approved for up to 60 days per each RBHA's (Regional Behavioral Health Authority) policy. For greater than 60 days, providers must submit a prior authorization request for continued utilization of concomitant use of two of the following antidepressants (excludes trazodone, mirtazapine or bupropion):
1. Two SSRIs
2. SSRI in combination with an SNRI
3. Two SNRIs
4. Two Tricyclics (TCAs)
5. TCA with SSRI/SNRI

Coverage is not authorized for:

1. Members with known hypersensitivity to the requested agent(s).
2. Members not meeting the above stated criteria.
3. Members currently taking an MAOI medication.
4. Members with significant polypharmacy or concomitant psychiatric/medical comorbidities that have a potential for adverse effects.
5. Members on medication combinations, doses, or for identified indications that do not meet published practice guidelines or treatment protocols.
6. Members on medication regimens that do not have adequate safeguards or monitoring to ensure safety and reasonable expectation of response to regimen.

References

Criteria last reviewed/updated 6/2019
Concomitant Antipsychotic Therapy will be considered for coverage under the Pharmacy benefit program when all of the following criteria are met:

1. Refractory schizophrenia spectrum disorder:
   a. Evidence of adequate trials of at least three (3) individual formulary antipsychotics, 4-6 weeks of maximum tolerated doses, and failure due to:
      1. Inadequate response to maximum tolerated dose
      2. Adverse reaction(s)
      3. Break through symptoms

2. Refractory bipolar disorder with psychosis and/or severe symptoms
   a. Evidence of adequate trials of at least four (4) evidence based treatment options dependent upon the episode type. Trials may include but not limited to combination therapy of antipsychotics and mood stabilizers and/or anticonvulsants. Trials should be 4-6 weeks of maximum tolerated doses, with failure due to:
      i. An inadequate response at maximum tolerated doses
      ii. Adverse reaction(s)
      iii. Breakthrough symptoms

3. Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials.

*Special Considerations:

- Cross tapers will automatically be approved for 60 days for members over 18 years of age. Providers must submit a prior authorization request for continued utilization of concomitant use of any 2 antipsychotics beyond the 60 days allowed for cross tapering.
- Documentation of all of the following are also required:
  - Treatment plan includes safety monitoring, evidence of clinical safety and baseline labs, vitals and routine monitoring including weight, BMI (body mass index), blood pressure, CBC including fasting glucose, fasting lipid panel within the last 12 months

Provider has shared results with the patient and primary care provider (PCP) and attestation that coordination of care is occurring if medication is prescribed by more than one provider (e.g., primary care, neurologist).

Coverage is not authorized for:

- Members with known hypersensitivity to the requested agent(s).
- Members not meeting the above stated criteria.
References


Criteria last reviewed/updated 6/2019
**Criteria Name**

Concomitant Anxiolytic Therapy -- Applies to all anxiolytics (formulary and non-formulary agents)

Formulary products include: alprazolam, buspirone, chlordiazepoxide, clorazepate, diazepam, lorazepam and oxazepam

**CRITERIA FOR COVERAGE/NONCOVERAGE**

Anxiolytic agents will be considered for concurrent or concomitant therapy coverage under the pharmacy benefit program when all of the following criteria are met:

a. Indication (diagnosis) for both drugs is consistent with FDA labeling or medical compendia (e.g. DrugDex)
b. Medical necessity of concomitant therapy is justified in clinical notes
c. Dosing of both drugs is consistent with clinical literature
d. No contraindications exists if used together
e. Prescriber of the two drugs is the same or if prescribers are not the same, each prescriber has been contacted and is aware of use of both drugs together
f. Documentation of CSPMP review is present in provider clinical notes or pharmacist reviewer case notes as deemed applicable by pharmacist. Review references safe and monitored use of agents concomitantly considering members current medication profile
g. If one drug is going to replace the other (taper on and taper off), the duration of use together is limited to less than 60 days. If yes, approve for 60 days or less. Taper dosing for changing to a different anxiolytic must be noted in the chart notes or pharmacist case notes with taper schedule included.

Authorization for continued use shall be reviewed at least every 12 months to confirm medical necessity and lack of contraindications to concomitant therapy.

**References**


Criteria last reviewed/updated 6/2019
Criteria Name

Concomitant Long Acting Opioid Therapy

Applies to all long acting opioids (formulary and non-formulary agents)

Formulary products include: Butrans, Embeda, Fentanyl patches, Morphine Sulfate ER tablets, Tramadol ER tablets, and Xtampza ER capsules

CRITERIA FOR COVERAGE/NONCOVERAGE

Long acting opioid agents will be considered for concurrent or concomitant therapy coverage under the pharmacy benefit program when all of the following criteria are met:

1. Indication (diagnosis) for both drugs is consistent with FDA labeling or medical compendia (e.g. DrugDex) and member requires around the clock pain relief.

2. Medical necessity of concomitant therapy is justified in clinical notes and no contraindications exist if used together.

3. Dosing of both drugs is consistent with clinical literature.

4. Prescriber of the two long acting agents is the same OR if prescribers are not the same, each prescriber has been contacted and is aware of use of both drugs.

5. Prescriber is aware of any short acting opioids (e.g., oxycodone, hydrocodone/APAP) or other controlled substances being used (e.g. benzodiazepines).

6. Submission of urinary drug screen labwork dated within the past 4 months.

7. Documentation prescriber has reviewed the member’s profile in the AZCSPMP.

8. If one drug is going to replace the other (taper on and taper off), the duration of use together is limited to less than 30 days. If yes, approve for 30 days. Taper dosing for changing to a different CR Opioid must be noted in the chart notes or pharmacist case notes with taper schedule included.

Authorization for continued use shall be reviewed at least every 6 months to confirm medical necessity and lack of contraindications to concomitant therapy.

References:
1. Micromedex/DRUGDEX at www.microdexsolutions.com
   Updated 7/2019
Short Acting (IR Formulations) Opioids will be considered for concurrent or concomitant therapy coverage under the pharmacy benefit program when the following criteria are met:

1. Medical necessity of concomitant therapy is justified in clinical notes and no contraindications exist if used together.

2. Dosing is consistent with clinical literature or FDA approved indication.

3. Submission of urinary drug screen labwork dated within the past 4 months.

4. Documentation prescriber has reviewed the member’s profile in the AZCSPMP.

5. Prescriber is aware of any other controlled substances being used.

6. No more than TWO prescriptions for TWO short acting opioids per 30 days.

7. If one drug is going to replace the other, the duration of use together and tapering schedule is included in chart notes.

Authorization for continued use shall be reviewed at least every 6 months to confirm there are no contraindications to therapy.

References
   Updated 7/2019
Criteria Name

Concomitant Sedative Hypnotic Therapy
Applies to all Sedative Hypnotics (formulary and non-formulary agents)
Formulary products include: estazolam, flurazepam, temazepam, triazolam, zaleplon and zolpidem

CRITERIA FOR COVERAGE/NONCOVERAGE

Sedative hypnotic agents will be considered for concurrent or concomitant therapy coverage under the pharmacy benefit program when all of the following criteria are met:

1. Indication (diagnosis) for both drugs is consistent with FDA labeling or medical compendia (e.g. DrugDex)
2. Medical necessity of concomitant therapy is justified in clinical notes
3. Dosing of both drugs is consistent with clinical literature
4. No contraindications exists if used together
5. Prescriber of the two drugs is the same OR If prescribers are not the same, coordination of care has occurred between providers, and each prescriber is aware of use of both drugs together
6. Documentation of CSPMP review is present in provider clinical notes or pharmacist reviewer case notes as deemed applicable by pharmacist. Review references safe and monitored use of agents concomitantly considering members current medication profile
7. If one drug is going to replace the other (taper on and taper off), the duration of use together is limited to less than 60 days. If yes, approve for 60 days or less. Taper dosing for changing to a different hypnotic must be noted in the chart notes or pharmacist case notes with taper schedule included.

Authorization for continued use shall be reviewed at least every 12 months to confirm medical necessity and lack of contraindications to concomitant therapy

References

Criteria last reviewed/revised: 6/2019
**Nonformulary**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>COSENTYX</td>
<td>secukinumab</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Cosentyx** is a self-administered subcutaneous injection of a human interleukin-17A antagonist indicated for the treatment of:

- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy
- Adults with active psoriatic arthritis (PsA)
- Adults with active ankylosing spondylitis (AS)

**COSENTYX** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Plaque Psoriasis (Adult)
   a. Prescribed by or in consultation with a dermatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of *moderate to severe* plaque psoriasis with ≥ 10% of body surface area (BSA) affected.

   **Note:** An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.

   e. Documentation member has failed topical therapy for a trial of at least 90 days and includes three of the following verified by prescription claims history:
i. Calcipotriene (generic for Dovonex) topical preparations

ii. Medium-to-high potency corticosteroids
   
   Note: For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.

iii. Tazorac topical gel 0.05%

iv. Tacrolimus 0.1% (prior authorization required) ointment

v. Coal tar preparations such as coal tar shampoo

f. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:

   i. Methotrexate oral tablets
   ii. Cyclosporine oral capsules
   iii. Acitretin capsules (generic for Soriatane) – prior authorization required

h. Current weight is documented and dated within the past 90 days and resulting dose calculated is consistent with the FDA labeled dosing.

i. Documentation submitted supporting Cosentyx will be self-administered by the member at a maintenance dosing interval of no less than every 12 weeks after the initial dosing of one injection at Week 0 and at Week 4.

2. Psoriatic arthritis

   a. Prescribed by or in consultation with a rheumatologist.

   b. Age ≥ 18 years.

   c. Documentation submitted member has no latent or active tuberculosis infection.

   d. Documented diagnosis of moderate to severe psoriatic arthritis and one or more of the following:

      x. Clinical Disease Activity Index (CDAI) > 10.0
      xi. Disease Activity Score 28 (DAS) ≥ 3.2
      xii. Simplified Disease Activity Index (SDAI) > 11.0

   e. Trial and failure of one of the following therapies unless intolerant or contraindicated:

      i. Methotrexate for ≥ 3 consecutive months

      ii. If documented intolerance or known contraindication to MTX, then one of the following disease-modifying antirheumatic agent for ≥ 3 consecutive months:
• Hydroxychloroquine
• Sulfasalazine
• Leflunomide

f. Prescribed concomitantly with MTX or another agent if intolerance or contraindication to MTX.

*Note:* Per 2015 ACR Treatment Guidelines for rheumatoid arthritis biologic therapy should be used in combination with methotrexate, when possible, due to superior efficacy of this combination over biologic monotherapy.

g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).

h. Current weight is documented and dated within the past 90 days and resulting dose calculated is consistent with the FDA labeled dosing.

i. Documentation submitted supporting Cosentyx will be self-administered by the member at a maintenance dosing interval of no less than every 12 weeks after the initial dosing of one injection at Week 0 and at Week 4.

j. Requested dose is for 45 mg unless documented co-existent moderate-to-severe plaque psoriasis exists and member weighs more than 100 kg, and if both are present then a dose of 90 mg is indicated instead.

3. Ankylosing Spondylitis

a. Prescribed by or in consultation with a rheumatologist.

b. Documentation submitted member has no latent or active tuberculosis infection.

c. Age ≥ 18 years old.

d. Documented diagnosis of ankylosing spondylitis.

e. Trial and failure, unless intolerant or contraindication, per documentation submitted and per prescription claims history of the following:

   i. Two or more prescription required non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, and for greater than 30 days.

   *Formulary NSAIDs include:* ibuprofen, naproxen, naproxen DR, piroxicam, diclofenac, meloxicam, nabumetone, oxaprozin, indomethacin, indomethacin ER, flurbiprofen, fenoprofen, and etodolac.

   *Note:* Oral NSAIDs are recommended as the first-line drug for ankylosing spondylitis per the 2016 ASAS/EULAR guidelines
f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both **Humira** (adalimumab) and **Enbrel** (etanercept).

g. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of **Cimzia** (certolizumab) or **Simponi** (golimumab).

h. Documentation submitted supporting Cosentyx will be self-administered by the member at a maintenance dose of 50 mg and dosing interval of no less than every 4 weeks.

**Approval Length:** Three months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits** (applicable for single-use vial, prefilled syringe, or Sensoready pen): Up to the maximum quantity allowed per the recommended dosing consistent with the FDA labeled prescribing information.

**Continuation Criteria:**

*Psoriasis (adult)* – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters based on decreased total percent BSA affected.

*Psoriatic arthritis* – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters by a result of at least one of the following disease activity measurements listed below.

- Clinical Disease Activity Index (CDAI) < 10.0
- Disease Activity Score 28 (DAS) ≤ 3.2
- Simplified Disease Activity Index (SDAI) < 11.0

*Ankylosing spondylitis* – Documentation submitted supporting decrease in at least one of the following

3. Back pain
4. Serum C-reactive protein

**Exclusions:**

1. Concomitant use with other biologic DMARD medications (oral and injectable).

2. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.

3. The following is a list of acceptable contraindications for the use of methotrexate:

- Pregnancy
- Actively breast-feeding
- Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
- Immunodeficiency syndrome
- Hepatitis B or C infection
- Liver enzymes that are persistently elevated
- Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider
**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:


Criteria effective: 10/01/2018; last reviewed April 2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARANESP</td>
<td>darbepoetinalfa</td>
</tr>
<tr>
<td>PROCRIT</td>
<td>epoetinalfa</td>
</tr>
<tr>
<td>EPOGEN</td>
<td>epoetinalfa</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

The above medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:
   a. Anemia associated with chronic kidney disease (includes those on dialysis and not on dialysis) that meets the following:
      i. Hemoglobin less than 10 g/dL reflected in labwork dated within the past 90 days
   b. Anemia in patients on myelosuppressive chemotherapy; where there is a minimum of at least two additional months of planned chemotherapy
      i. Hemoglobin less than 10 g/dL reflected in labwork dated within the past 90 days
   c. Anemia in Zidovudine-treated HIV infected patients (Epogen/Procrit only)
      i. Endogenous serum erythropoietin levels less than or equal to 500 mUnits/mL.
   d. Reduction of allogeneic RBC transfusion in patients undergoing elective noncardiac, nonvascular surgery (Epogen/Procrit only) who are at high risk for perioperative blood loss
      i. Hemoglobin greater than 10 g/dL but less than or equal to 13g/dL reflected on labwork dated within the past 30 days.
   e. Anemia associated with Hepatitis C in members receiving ribavirin and interferon alfa or ribavirin and peginterferon alfa therapy (Epogen/Procrit only)
      i. Hemoglobin less than 10 g/dL reflected in labwork dated within the past 90 days.
   f. Anemia of chronic disease (i.e. rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease)(Epogen/Procrit only)
      i. Hemoglobin less than 12 g/dL and hematocrit less than 33 reflected in labwork dated within the past 90 days.
   g. Anemia due to primary myelofibrosis, post-polycythemia vera myelofibrosis, or post essential thrombocythemia myelofibrosis
i. The member is symptomatic from the anemia
ii. Hemoglobin less than 10 g/dL reflected in labwork dated within the past 90 days

2. Iron stores adequate (ferritin >100 ng/mL or transferrin saturation > 20%)

3. For ARANESP and EPOGEN, member must have tried and failed PROCRIT.

Authorization for continued use shall be reviewed at least every 3 months.

References
Criteria last reviewed: March 2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>DDAVP</td>
<td>desmopressin nasal</td>
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</table>

**ITERIA FOR COVERAGE/NONCOVERAGE**

**DDAVP / desmopressin nasal** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Diagnosis of Central (cranial) diabetes insipidus

Authorization is for 12 months

**References**


Criteria last reviewed and updated: 02/2019
Diclofenac topical gel is FDA approved as a nonsteroidal anti-inflammatory drug (NSAID) for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. The total dose should not exceed 32 g per day. Per the FDA label it was not evaluated for use on joints of the spine, hip, or shoulder.

**Diclofenac 1% topical gel** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has been diagnosed with pain associated with osteoarthritis of joints receptive to topical treatment, such as the knees, ankles, feet, hands, elbows, and wrists.

2. Member meets **one** of the following criteria below:
   a. Member has tried and failed an adequate course of therapy with at least **two** oral generic prescription formulary NSAID agents. Trial defined as a 30 day trial.

   *Formulary NSAIDs include:* ibuprofen, naproxen, naproxen DR, piroxicam, diclofenac, meloxicam, nabumetone, oxaprozin, indomethacin, indomethacin ER, flurbiprofen, fenoprofen, and etodolac.

   **Note:** Meloxicam, nabumetone, and etodolac are partially selective COX-2 inhibitors at lower doses and some evidence supports they exhibit better gastrointestinal tolerance at lower doses.

   b. Member has a documented contraindication to oral NSAID therapy such as a history of gastric or duodenal ulcers, concomitant anticoagulant or antiplatelet therapy, including warfarin and aspirin, or has severe gastroesophageal reflux disease.

**Approval length:** 12 months.

<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Reference Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac 1% Gel</td>
<td>VOLTAREN 1% Gel</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**
**Continuation criteria:** Authorization for continued use shall be reviewed at least every 12 months to confirm documentation of the absence of contraindications and the presence of a clinical response to therapy.

**References:**


Criteria reviewed and revised March 2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>DIFICID</td>
<td>fidaxomicin</td>
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</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**DIFICID/fidaxomicin** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a diagnosis of clostridioides difficile infection and is greater than 18 years old.

2. Member must have documented trial and failure, intolerance or contraindication to vancomycin.

3. Dificid is prescribed by, or in consultation with, an infectious disease provider or gastroenterologist.

**Approval Time Period: 10 days**

**References**


Criteria last reviewed and updated: March 2019
Donepezil and donepezil ODT are acetylcholinesterase inhibitors indicated for the treatment of dementia of the Alzheimer’s type. Efficacy has been demonstrated in patients with mild, moderate, and severe Alzheimer’s disease.

A dose of 10 mg once daily can be administered once patients have been on a daily dose of 5 mg for 4 to 6 weeks.

A dose of 23 mg once daily can be administered to patients with moderate to severe disease once they have been on a dose of 10 mg once daily for at least 3 months.

**Donepezil tablets and ODT in the 5 mg and 10 mg strengths will be considered for coverage under the pharmacy benefit program when the following criteria are met:**

1. Member must be 18 years old or older.
2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.
3. Documented diagnosis of mild, moderate, or severe dementia associated with Alzheimer’s disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
   a. Between 21 - 24 points for mild disease.
   b. Between 13 - 20 points for moderate disease.
   c. Less than 12 points for severe disease.

   OR

   Documented diagnosis of multi-infarct (vascular) dementia and brain imaging confirms evidence of cerebrovascular disease (CVD). Cognitive screening test results such as MMSE, mini-cog, 7 minute screen, Montreal Cognitive Assessment (MOCA) or SLUMS must be included.

**Donepezil 23 mg tablets will be considered for coverage under the pharmacy benefit program when the following criteria are met:**

<table>
<thead>
<tr>
<th>Covered products</th>
<th>Brand or generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donepezil tablets 5, 10 mg</td>
<td>ARICEPT</td>
</tr>
<tr>
<td>Donepezil orally disintegrating tablets 5, 10 mg</td>
<td>ARICEPT ODT</td>
</tr>
<tr>
<td>Donepezil tablets 23 mg</td>
<td>ARICEPT</td>
</tr>
</tbody>
</table>
1. All of the above criteria has been met and the member has moderate to severe dementia associated with Alzheimer’s disease as defined by an MMSE score of 20 or less.

2. The member has recent documented prescription claim history of donepezil tablets or ODT 5 mg or 10 mg for three consecutive months.

Use of donepezil in combination with memantine will be considered for coverage when the following criteria are met:

1. Notation of moderate to severe disease.

2. Notation that the member failed to respond to, or had an inadequate response to compliant use of monotherapy for at least 60 days.

Quantity Limits: #30 per 30 days

Length of Approval: Six months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

Continuation Criteria:

1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score for dementia related to Alzheimer’s Disease.

2. Documentation member is receiving a positive clinical response evidenced by an improvement in cognitive testing for vascular dementia.

Exclusions:

1. Not for use for other non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.

2. Use of doses greater than 23mg per day.

References:


<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>JANUVIA</td>
<td>sitagliptin</td>
</tr>
<tr>
<td>JANUMET / JANUMET XR</td>
<td>sitagliptin/metformin</td>
</tr>
<tr>
<td>TRADJENTA</td>
<td>linagliptin</td>
</tr>
<tr>
<td>JENTADUETO</td>
<td>linagliptin/metformin</td>
</tr>
<tr>
<td>KOMBIGLYZE XR</td>
<td>Saxagliptin/metformin</td>
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<tr>
<td>ONGLYZA XR</td>
<td>saxagliptin</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

Januvia, Janumet, Janumet XR, Tradjenta, Jentadueto, Onglyza, and Kombiglyze XR will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Baseline A1c or goals of therapy
2. The member has diagnosis Type 2 Diabetes Mellitus (DMII)
   - Failure to obtain adequate glycemic control (A1c) after at least a 2 months (60 days) trial of maximum tolerated dose of metformin
   OR
   - Member is unable to take metformin due to intolerance (defined as ongoing GI problems (diarrhea, nausea, abdominal cramping) OR has contraindication (e.g., eGFR below 30mL/min).
3. Requested medication will not be used in combination with a GLP-1 agonist (e.g., exenatide (Byetta, Bydureon), liraglutide (Victoza), semaglutide (Ozempic, Rybelsus).

*Note: The American Diabetes Association (ADA) 2019 standards of medical care in diabetes do not recommend the use of GLP-1 receptor agonists in combination with DPP-4 inhibitors due to lack of or insufficient data regarding their combined use.*

Initial approval duration: 6 months

Continuation Criteria:

1. Member had improvement in target goals (a reduction in hemoglobin A1c, glucose levels) since starting this therapy (3-6 months) and does not have adverse effects or contraindications.

Continuation approval duration: 12 months
Exclusion:
- Pre-diabetic patients (e.g., HbA1c ≥ 5.7% and FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L) OR HbA1c <5.7%).

References:

### Dupixent

**Brand Name**: Dupixent  
**Generic Name**: dupilumab

### CRITERIA FOR COVERAGE/NON-COVERAGE

**Dupixent** is an interleukin-4 receptor alpha antagonist indicated for:

- The treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

- As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma

Dupixent will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

**Atopic dermatitis**

1. Documentation submitted supporting diagnosis of an adult with chronic moderate-to-severe atopic dermatitis (according to American Academy of Dermatology Consensus Criteria) and meets all of the following:
   a. Documentation of greater than or equal to 10% body surface area (BSA) of atopic dermatitis involvement.
   b. Documented baseline EASI (Eczema Area and Severity Index) score of 25.
   c. Documented baseline Pruritus NRS score ≥ 4.
   d. Documented recent history of trial and failure (within 6 months) with either inadequate response after trial of 90 days, intolerance, or contraindication to all of the following:
      i. Treatment with a moderate to very high potency topical corticosteroid.
      ii. Treatment with a topical calcineurin inhibitor such as Elidel or Protopic (prior authorization required)
      iii. Oral cyclosporine or methotrexate
      iv. Localized phototherapy with ultraviolet B (UVB) or UVA light (PUVA).

2. Prescribed by, or in conjunction with a Dermatologist, Allergist, or Immunologist.

**Asthma**

1. Prescribed by, or in consultation with an allergist, immunologist, or pulmonologist.
2. Documentation supporting diagnosis of persistent moderate to severe asthma. Persistent moderate to severe asthma defined as asthma symptoms that are symptomatic consistently with 1 to 2 or more exacerbations in the past 12 months.

3. Lab documentation of baseline (prior to treatment) blood eosinophil count that is > 300 cells/microliter in the past 12 months.

4. Documentation submitted supports member’s symptoms are not adequately controlled with high-dose inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA) for at least 3 months.

5. Member has been adherent within a 12 month period, and is currently adherent, with asthma therapy verified per prescription claims history and/or chart notes if prescription claims history is not supportive.

6. Documentation submitted supporting if member is a current nicotine smoker or not and if so are engaged in smoking cessation efforts. Smoking cessation efforts may include use of prescription medication, topical patches, and counseling.

**Chronic Rhinosinusitis with Nasal Polyps:**

1. Prescribed by, or in consultation with an allergist or immunologist
2. Documentation supporting diagnosis of chronic rhinosinusitis with nasal polyps.
   i. Chronic sinusitis: 22-item sino-nasal outcome test (SNOT-22) score ≥ 50
   AND
   ii. Nasal polyps: bilateral endoscopic nasal polyp score ≥ 4
3. Trial and failure of ALL of the following
   i. saline nasal irrigation
   ii. intranasal corticosteroid
4. Documentation of allergy and immune function testing
   iii. allergy skin testing
   iv. IgG, IgA, IgM, and T-cell number and function
5. Intranasal corticosteroids MUST be continued during Dupixent treatment.
6. Dose not to exceed 300mg every two weeks

**Continuation Criteria for atopic dermatitis:** Authorization for continued use shall be reviewed to confirm all of the following have occurred and are supported with documentation.

1. Reduction in EASI scores from baseline by 25%.
2. Significant change in pruritus defined as decrease in Pruritus NRS score by 50%.
3. Decrease in affected body area from baseline by 50%.
4. Consistent prescription fill history of Dupixent.

**Continuation criteria for asthma:**
1. Prescriber attestation supporting any **one** of the following:
   a. Decreased incidence of asthma exacerbations.
   b. Decreased need for use of rescue medications.
   c. Decrease need for systemic corticosteroids.
   d. Decrease in hospitalizations/emergency room visits.
   e. Improvement in FEV1 from baseline.
2. Member has continued adherence with asthma therapy (inhalers, oral medications) as verified per prescription claims history and/or chart notes if prescription claims history is not supportive.

**Exclusions:**
1. Member is not receiving combined concomitant treatment of Dupixent with Xolair, Nucala, Cinqair, or Fasenra.

**Approval Length:** Initial approval for 3 months to evaluate response, further approvals may be extended to 12 months dependent on clinical response.

**References:**

Criteria last revised 6/2019
<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Approved Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>dutasteride</td>
<td>Avodart</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

*Dutasteride* will be considered for coverage under the pharmacy benefit program when both of the following criteria are met:

1. The member has a diagnosis of Benign Prostatic Hyperplasia (BPH)

2. Member must try and fail finasteride in combination with tamsulosin

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

**References**


Criteria last reviewed: March 2019
Elmiron capsules are indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. The above medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member is an adult with a documented diagnosis of interstitial cystitis/bladder pain syndrome and both of the following:
   a. Pain, pressure, or discomfort associated with lower urinary tract symptoms are present for 6 weeks or longer
   b. Absence of infection or other identifiable cause
2. Documentation of inadequate response to conservative therapy (e.g. bladder training, pelvic floor rehab, biofeedback, etc.)
3. Documented inadequate response or inability to tolerate one of the following supported by prescription claims history and chart notes:
   a. Amitriptyline
   b. Cimetidine
   c. Hydroxyzine

Approval Length: 3 months initially and then up to 12 months thereafter dependent on clinical response.
Quantity Limits: Up to #90 per 30 days (one capsule three times a day).
Continuation Criteria: Documented positive response to therapy evidenced by a decrease in pain symptoms (pressure and discomfort).

References:
Criteria effective 10/01/2018. Last reviewed and revised: March 2019
**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Emflaza** is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older. The recommended once daily dose is 0.9 mg/kg/day.

*Emflaza* will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by, or in consultation with, a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

2. Member is 5 years of age or older.

3. Documented diagnosis of Duchenne muscular dystrophy (DMD) confirmed by the presence per laboratory report of either abnormal dystrophin or a confirmed mutation of the dystrophin gene

4. Documentation of onset of weakness before 5 years of age.

5. One of the following must be met:
   a. Intolerable side effect(s) to prednisone or prednisolone after a trial of two months and after attempts of dose reduction or alternative dosing regimens. Intolerable side effects defined as any of the following (documentation required):
      i. Undesirable weight gain defined as a ≥ 10% of body weight gain increase over a 6-month period.
      ii. Diabetes and/or hypertension that is difficult to manage according to the prescribing physician.
      iii. A severe behavioral health adverse effect while on prednisone therapy that has or would require a prednisone dose reduction.

6. Documentation of baseline motor milestone scores by one of the following assessments:
   - 6-minute walk test (6MWT)
   - North Start Ambulatory Assessment (NSAA)
   - Motor Function Measure (MFM)
   - Hammersmith Functional Motor Scale (HFMS)
   - Pulmonary function tests

**Approval Length:** Six months initially then 12 months thereafter dependent on clinical response.

**Quantity Limits:** 30 tablets per 30 days based on the current weight submitted for the member. For the oral suspension the appropriate volume quantity per 30 days should be calculated based on the current weight. Dose prescribed should not exceed 0.9 mg/kg/day.
Continuation Criteria: Documentation of initial improvement for any one of the following tests and then continued improvement or stabilization.

- 6-minute walk test (6MWT)
- North Start Ambulatory Assessment (NSAA)
- Motor Function Measure (MFM)
- Hammersmith Functional Motor Scale (HFMS)
- Pulmonary function tests (FEV1 or FVC)

References:


Criteria created Mar 2018
**EMSAM** is a monoamine oxidase inhibitor (MAOI) indicated for the treatment of major depressive disorder (MDD).

The patch is applied once every 24 hours to the upper torso. The recommended starting dose and target dose is 6 mg per 24 hours.

**Emsam** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. A documented diagnosis of major depressive disorder (MDD).

2. The member is over the age of 18 years old.

3. A documented trial evidenced by prescription claims history of at least 30 days and failure per chart notes of or intolerance to **four** of following formulary alternatives at maximum therapeutic or tolerated dose and must include one SSRI and one SNRI:

   **Formulary Alternatives:** Escitalopram, citalopram, fluoxetine, fluvoxamine (including extended-release), paroxetine (including extended-release), sertraline, venlafaxine (including extended-release), duloxetine (20, 30, and 60 mg), desvenlafaxine, bupropion, and mirtazapine.

4. A documented trial evidenced by prescription claims history of at least 30 days and failure of or intolerance documented by chart notes to one of the following at a maximum therapeutic or tolerated dose:
   a. Phenelzine
   b. Tranylcypromine
   c. Isocarboxazid

**Quantity limits:** #30 per 30 days

**Approval Length:** 12 months
Continuation criteria:

1. Attestation member is receiving a positive clinical response to Emsam therapy.

Exclusions:

1. Use concurrently with bupropion, SSRI, SNRI, tricyclic antidepressant (TCA), meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, other MAO inhibitors, and carbamazepine. These drugs are contraindicated for use with Emsam.

References:

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<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENBREL – Preferred Product</td>
<td>etanercept</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

*Enbrel* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of **moderate to severe** rheumatoid arthritis (RA) per chart notes or provider attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Hydroxychloroquine
      iii. Leflunomide
      iv. Sulfasalazine
   f. Dosing requested is 50 mg injected once a week.

2. **Juvenile Idiopathic Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 2 years and current weight is ≥ 10 kg.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of **moderate to severe** rheumatoid arthritis (RA) with at least five swollen joints and at least three joints with limitation of motion.
   e. Trial and failure of **one** of the following therapies unless intolerant or contraindicated
      i. Methotrexate for at least 30 days
      ii. Oral NSAID for at least 30 days
      iii. Oral corticosteroid for at least 14 days
   f. Dosing requested is based on a current weight submitted and is consistent with 0.8 mg/kg once a week with a maximum dose of 50 mg per week.

3. **Adult Plaque Psoriasis**
   a. Prescribed by or in consultation with a dermatologist or rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of **moderate to severe** plaque psoriasis with ≥ 10% of body surface area (BSA) affected.

   **Note:** An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with **moderate to severe** plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.
e. Documentation member has failed topical therapy for a trial of at least 90 days and includes two of the following verified by prescription claims history:
   i. Calcipotriene (generic for Dovonex) topical preparations
   ii. Medium-to-high potency corticosteroids
      Note: For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
   iii. Tacrolimus 0.1% (prior authorization required) ointment
   iv. Coal tar preparations such as coal tar shampoo
f. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
   i. Methotrexate oral tablets
   ii. Cyclosporine oral capsules
g. Dosing requested is 50 mg twice a week for the first 3 months followed by 50 mg once a week.

4. Pediatric Plaque Psoriasis
a. Prescribed by or in consultation with a dermatologist or rheumatologist.
b. Age ≥ 4 years.
c. Documentation submitted member has no latent or active tuberculosis infection.
d. Documented diagnosis of **moderate to severe** plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
   Note: An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.
e. Documentation member has failed topical therapy for a trial of at least 90 days and includes two of the following verified by prescription claims history:
   vi. Calcipotriene (generic for Dovonex) topical preparations
   vii. Medium-to-high potency corticosteroids
      Note: For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
   viii. Tacrolimus (prior authorization required) ointment
   ix. Coal tar preparations such as coal tar shampoo
f. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
   iv. Methotrexate oral tablets
   v. Cyclosporine oral capsules
g. Dosing requested is based on a current weight submitted and is consistent with 0.8 mg/kg once a week with a maximum of 50 mg per week.

5. Psoriatic Arthritis
a. Prescribed by or in consultation with a dermatologist or rheumatologist.
b. Age ≥ 18 years.
c. Documentation submitted member has no latent or active tuberculosis infection.
d. Documented diagnosis of **moderate to severe** psoriatic arthritis (PsA) per chart notes or prescriber attestation.
e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
i. Methotrexate
ii. Leflunomide
iii. Sulfasalazine
f. Dosing requested is 50 mg injected once a week.

6. Ankylosing Spondylitis:
   a. Prescribed by or in consultation with a rheumatologist.
   b. Documentation submitted member has no latent or active tuberculosis infection.
   c. Age ≥ 18 years old.
   d. Documented diagnosis of ankylosing spondylitis.
   e. Trial and failure, unless intolerant or contraindication, per documentation submitted and per prescription claims history of the following:
      i. Two or more prescription required non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, and for greater than 30 days.

      Formulary NSAIDs include: ibuprofen, naproxen, naproxen DR, piroxicam, diclofenac, meloxicam, nabumetone, oxaprozin, indomethacin, indomethacin ER, flurbiprofen, fenoprofen, and etodolac.

      Note: Oral NSAIDs are recommended as the first-line drug for ankylosing spondylitis per the 2016 ASAS/EULAR guidelines

   f. Dosing requested is 50 mg injected once a week.

Approval Length: Six months initially for all diagnoses. Up to one year thereafter based on clinical response documented.

Quantity Limits:
1. Ankylosing spondylitis, juvenile idiopathic arthritis, psoriatic arthritis and rheumatoid arthritis:
   Enbrel 25 mg syringe – 8 syringes per 28 days
   Enbrel 50 mg syringe – 4 syringes per 28 days
2. Plaque psoriasis:
   Enbrel 25 mg syringe – 16 syringes per 28 days (initial 12 weeks) then 8 syringes per 28 days thereafter
   Enbrel 50 mg syringe – 8 syringes per 28 days (initial 12 weeks) then 4 syringes per 28 days thereafter

Continuation Criteria: Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.

Exclusions/Limitations:
1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
2. Concomitant use with other biologic medications is considered experimental and investigational.
3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
- Hepatitis B or C infection
- Liver enzymes that are persistently elevated
- Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**Congestive heart failure and the use of TNF inhibitors**

The ACR 2015 Treatment Guidelines for rheumatoid arthritis notes there are no reports of exacerbation of heart failure using non-TNF biologics and the US Food and Drug Administration (FDA) warns against using TNF inhibitors in this population based on worsening of congestive heart failure with TNF inhibitors in the Adverse Event Reporting System database. A TNF inhibitor should only be used if there are no other reasonable options, and then, perhaps, only in compensated heart failure.

**Malignancies and the use of TNF inhibitors**

ACR 2015 Treatment Guidelines for rheumatoid arthritis for previously treated or untreated skin cancer (melanoma or non-melanoma) and for previously treated lymphoproliferative disorders state as a recommendation to not use a TNF inhibitor. For previously treated solid organ malignancy the recommendations for treatment are the same as for patients without this condition.

**Previous Serious Infections and the use of TNF inhibitors**

Per the ACR 2015 Treatment Guidelines for rheumatoid arthritis there was no consensus for making a recommendations regarding the use of other non-TNF biologics over TNF inhibitors in this setting.

**References:**


Criteria revised: May 2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>ENTRESTO</td>
<td>sacubitril/valsartan</td>
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</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Entresto** is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker, indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

**Entresto** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The initial prescription has been written by a cardiologist. Refills may be written by the primary care provider.
2. Member has a documented diagnosis of chronic heart failure NYHA class II to IV.
3. Documented reduced ejection fraction (EF) of less than or equal to 40%.
4. Member will not be taking a concomitant ACE inhibitor, ARB or aliskiren.
5. Member does not have a history of angioedema with previous ACE inhibitor or ARB therapy.
6. The member must have had a trial of an ACE inhibitor or ARB for at least 4 weeks.

**Approvable quantity:** Up to 60 tablets per 30 days.

**Approval length:** 12 months.

**Continuation criteria:** Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy and there is a documented clinical response.

**References:**

Criteria revised: March 2019
Brand Name | Generic Name
---|---
ESBRIET | pirfenidone

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Esbriet (pirfenidone)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has

1. Diagnosis of idiopathic pulmonary fibrosis; AND
2. Prescriber must be a pulmonologist; AND
3. Monitoring liver function (LFT’s) AND
4. Dosing consistent with guidelines

The recommended daily maintenance dosage of ESBRIET is 801 mg (three 267 mg capsules) three times a day with food for a total of 2403 mg/day. Doses should be taken at the same time each day.

Upon initiation of treatment, titrate to the full dosage of nine capsules per day over a 14-day period as follows:

| Dosage Titration for ESBRIET in Patients with IPF |
| --- | --- |
| Treatment days | Dosage |
| Days 1 through 7 | 1 capsule three times a day with food |
| Days 8 through 14 | 2 capsules three times a day with food |
| Days 15 onward | 3 capsules three times a day with food |

Dosages above 2403 mg/day (9 capsules per day) are not recommended for any patient.

**Exclusion to Coverage:**

- The patient exhibits >3 but ≤5 × ULN ALT and/or AST accompanied by symptoms or Hyperbilirubinemia.

Authorization will be for duration of 12 months. Reauthorization requires documentation of response to therapy. This guideline will be reviewed on an annual basis.

**References**


Criteria last reviewed and updated: 6/2019
**Non Formulary**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUCRISA</td>
<td>crisaborole</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Eucrisa** 2% topical ointment is a phosphodiesterase 4 inhibitor indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older. Recommended dosage is application twice a day to affected areas.

**Eucrisa** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Documented diagnosis of atopic dermatitis.
2. Member is age 2 years of age or older.
3. Documentation of a trial and failure, intolerance of, or contraindication to, a two week trial of two generic formulary medium to high potency topical corticosteroids. For areas involving the face, neck, or intertriginous areas a trial of at least two low potency topical corticosteroids can be utilized.
4. Documentation of a trial and failure, intolerance of, or contraindication to, a two week trial of tacrolimus ointment (prior authorization required) or Elidel cream (prior authorization required).

<table>
<thead>
<tr>
<th>Class</th>
<th>Drug</th>
<th>Dosage Form</th>
<th>Strength (%)</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td>clobetasol propionate</td>
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<td></td>
<td>diflornasone diacetate</td>
<td>Ointment</td>
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<td></td>
<td>halobetasol propionate</td>
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<td>Cream</td>
<td>0.05</td>
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<td>betamethasone dipropionate</td>
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<td></td>
<td>halocinonide</td>
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<td>mometasone furoate</td>
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<td>triamcinolone acetonide</td>
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<td>triamcinolone acetonide</td>
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<td>fluocinolone acetonide</td>
<td>Cream, soln</td>
<td>0.01</td>
<td></td>
</tr>
</tbody>
</table>

**Approval Length:** Three months initially then up to twelve months thereafter based on clinical response.

**Quantity Limits:** One 60 gm tube per 30 days.

**Continuation Criteria:**
1. Documentation supporting the atopic dermatitis has not worsened while on therapy. Worsening defined as:
   - Red, scaly, itchy and crusted bumps
   - Cracking of skin and seeping of clear fluid
   - Coarsening and thickening of the skin

**References:**

**Criteria effective:** March 2019

**Additional notes:**
- Atopic dermatitis is a chronic, pruritic inflammatory skin disease. It is often associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and asthma.
- Treatment guidelines recommend the use of **topical corticosteroids** in patients who have failed to respond to good skin care and regular use of emollients alone.
- **Topical calcineurin inhibitors**, tacrolimus and Elidel, are recommended as second-line agents. Guidelines recommend using topical calcineurin inhibitors in the following situations:
  - Patients’ refractory to topical corticosteroids,
  - Use in sensitive areas (e.g. face, axilla, anogenital region, and skin folds)
  - Patients with steroid induced-atrophy
  - Patients who require long-term treatment
- Goals of treatment include clearance of skin lesions, control of itch, prevention of adverse events and triggers associated with various treatment modalities, and preventing future exacerbations.

**Efficacy:**
Has only been evaluated against placebo per the FDA approved clinical trials.
Two identical multicenter, randomized, double blind, vehicle-controlled trials. In both trials, subjects were randomized to receive crisaborole or vehicle applied twice daily for 28 day. The primary endpoint in both studies was treatment success, which was defined as an Investigator’s Static Global Assessment (IGSA) score of clear (0) or almost clear (1) with a 2-grade or greater improvement from baseline.
In both studies, treatment with resulted in statistically significant improvement in treatment success compared to placebo.

Guidelines:
Guidelines state the majority of patients can achieve clinical improvement and disease control with nonpharmacologic interventions, conventional topical therapies (including corticosteroids and calcineurin inhibitors), and environmental modifications.
Topical corticosteroids are recommended for in patients who have failed to respond to good skin care and regular use of emollients alone. They are the mainstay of care and have a long history of use. Overall, they are well tolerated, but prolonged use may result in skin atrophy and continued use of higher potency topical corticosteroids may cause systemic side effects, although the risk is low.
Topical calcineurin inhibitors are recommended and effective for acute and chronic treatment. Both topical tacrolimus and pimecrolimus are FDA-approved as second-line agents.
Topical calcineurin inhibitors may be preferred to topical corticosteroids in the following situations: patients’ refractory to topical corticosteroids, use in sensitive areas (e.g. face, axilla, anogenital region, and skin folds), patients with steroid induced-atrophy, and in patients who require long-term treatment.
Topical calcineurin inhibitors are well tolerated but contain a boxed warning for malignancy. Rare cases of malignancy (e.g., skin cancer and lymphoma) have been reported.
Guidelines have not addressed the role of crisaborole (Eucrisa).

Investigational Uses
Several small studies have evaluated crisaborole (Eucrisa) for the treatment of plaque psoriasis; however, the majority of studies were early phase studies and results are not available.

Atopic dermatitis (eczema) signs and symptoms vary widely from person to person and include:

- Dry skin
- Itching, which may be severe, especially at night
- Red to brownish-gray patches, especially on the hands, feet, ankles, wrists, neck, upper chest, eyelids, inside the bend of the elbows and knees, and in infants, the face and scalp
- Small, raised bumps, which may leak fluid and crust over when scratched
- Thickened, cracked, scaly skin
- Raw, sensitive, swollen skin from scratching

Atopic dermatitis most often begins before age 5 and may persist into adolescence and adulthood. For some people, it flares periodically and then clears up for a time, even for several years.
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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</thead>
<tbody>
<tr>
<td>EURAX</td>
<td>crotamiton</td>
</tr>
<tr>
<td>SKLICE</td>
<td>ivermectin</td>
</tr>
<tr>
<td>Natroba</td>
<td>spinosad</td>
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</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Eurax/crotamiton** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Diagnosis of Scabies
- Member had trial and failure of permethrin 5% (generic Elimite).

**Sklice (Ivermectin) topical lotion and Spinosad topical suspension** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Diagnosis of topical treatment of head lice infestations
- Member had trial and failure of Permethrin 1% (Over-the-counter (OTC) Nix); Pyrethrins/Piperonyl butoxide topical (Over-the-counter (OTC) Rid)
- Sklice: Age 6 months and older
- Spinosad: Age 4 years and older

Member must meet following for continuation of coverage:

- Member has developed a recurrent infestation.

Re-authorization duration: 1 month.

References:


Criteria last reviewed/updated: March 2019
Certain drugs are excluded or restricted from coverage under the Pharmacy Benefit per section 1927(d)(2) of the Social Security Act. The following below is a list of those medications.

1. DESI drugs – Drugs classified as Drug Efficacy Study implementation Drugs (DESI) by the Food and Drug Administration (FDA)

2. Sexual and Erectile dysfunction drugs – Drugs prescribed solely to treat the condition of sexual dysfunction or erectile dysfunction or impotency.

3. Fertility drugs – Drugs prescribed to promote fertility are excluded.

4. Cosmetic drugs – Drugs solely for cosmetic purposes including hair growth are excluded.  
   *Note: Treatments indicated for psoriasis, acne, rosacea are not considered cosmetic.*

5. Weight loss – Drugs prescribed for anorexia, weight loss, or weight gain are excluded.

6. Medical Marijuana.

7. Non-FDA approved drugs – Drugs that are not approved by the FDA. This includes drugs not assigned a National Drug Code (NDC).

8. Experimental Medications

9. Drugs eligible for coverage under Medicare Part D for AHCCCS members eligible for Medicare whether or not the member obtains Medicare Part D coverage.

References:

Criteria last reviewed: September 2019
Ezetimibe will be considered for coverage when the following criteria are met:

- Age 10 years of age or older
- Diagnosis of Familial hypercholesterolemia, Mixed hyperlipidemia, Primary hypercholesterolemia, and/or Homozygous Sitosterolemia
- Member had a 3 month trial (90 days) of two high-potency statins (atorvastatin 80 mg/day, rosvastatin 40 mg/day) OR
- Member has intolerance or contraindication to Statin therapy.

Contraindication/intolerance to a high intensity statin defined as ONE of the following:

- A labeled contraindication to all statins as documented in medical records OR
- Member has experienced documented rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN OR
- Member has undergone a trial of a statin re-challenge (i.e., pravastatin 10-40 mg or rosvastatin 5 mg) with documented reappearance of muscle symptoms such as myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks) OR
- Member is unable to tolerate low-, moderate-, and high-intensity statins as evidenced by documented myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks)

Initial approval duration: 12 months

Member must meet following for reauthorization:

- Member had improvement in lipids after initiation of therapy

Reauthorization approval duration: 12 months.

References:

Criteria created February 2019
Febuxostat is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. It is not recommended for the treatment of asymptomatic hyperuricemia.

Febuxostat will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Documented diagnosis of symptomatic hyperuricemia with a baseline (within the past 30 days) serum uric acid level ≥ 6 mg/dL. Symptoms defined as acute gout attack(s), tophi, and chronic gouty arthritis.
2. Member is ≥ 18 years of age.
3. Documented trial and failure, or intolerance of allopurinol in the previous 180 days up to a daily dose of at least 600 mg, or to a max dose based on any renal impairment, for at least 3 months.
   
   **Note:** Gradual upward titration should occur every 2 to 5 weeks for the allopurinol maintenance dose to an appropriate maximum dose for gout, in order to treat to the serum urate target appropriate for the individual patient.

   **Note:** American College of Rheumatology recommends a starting dose of allopurinol of no more than 100 mg daily and an even lower starting dose of 50 mg daily if CKD is evident.

4. Intolerance of allopurinol defined as:
   - Appearance of a skin rash or hypersensitivity reasons
   - Angioimmunoblastic lymphadenopathy
   - Granulomatous hepatitis
   - Documented continued GI distress even when taken after meals. GI distress defined as diarrhea, nausea, and vomiting.

5. Titration up to Uloric 80 mg daily requires documentation of failure to obtain serum acid level to less than 6 mg/dL after trial of Uloric 40 mg.

**Approval Length:** Three months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits:** Thirty tablets (30) per thirty (30) days.

**Continuation Criteria:**
1. Lab documentation submitted supports serum uric acid level less than 6 mg/dL while adherent to Uloric per prescription claim history and documentation of a reduced frequency of gout attacks.

**References:**

Criteria last reviewed: 6/2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>FEMRING</td>
<td>estradiol vaginal ring</td>
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</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

_Femring / estradiol vaginal ring_ will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses:
   a. Moderate to severe vasomotor symptoms associated with menopause
   b. Moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause.

2. There is documentation of the member’s trial and failure or contraindication to two formulary estrogen products (e.g., estradiol oral, vaginal cream (generic Estrace); Estring (estradiol vaginal ring), Yuvafem (generic Vagifem), Menest, Premarin tablet, Climara Pro patch).

**Quantity Limit:** One ring per 3 months

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

Criteria last reviewed/updated: March 2019
Forteo is recombinant human parathyroid hormone analog (1-34), [rhPTH (1-34)] indicated for:
- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture

Tymlos is a human parathyroid hormone related peptide [PTHrP (1-34)] analog indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, multiple risk factors for fracture, or for patients who have failed or are intolerant to other available osteoporosis therapies.

Forteo will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by or in consultation with a rheumatologist or endocrinologist.
2. The member has one of the following documented diagnoses:
   a. Postmenopausal osteoporosis in women who are at high risk of fracture.
   b. Osteoporosis that is primary (idiopathic) or hypogonadal in men who are at high risk of fracture.
   c. Osteoporosis associated with sustained systemic glucocorticoid therapy at high risk of fracture and history of prednisone use or its equivalent verified per prescription claims history at a dose of ≥ 5 mg/day for ≥ 3 months.
3. Osteoporosis diagnosis is supported by submitted documentation of one of the following:
   a. A current hip or vertebral fracture that is clinically apparent or found upon vertebral imaging.
   b. A T-score ≤ −2.5 at the femoral neck, total hip, or lumbar spine dated within the past 12 months.
   c. Low bone mass (T-score between −1.0 and −2.5 at the femoral neck or lumbar spine) and a 10-year probability of a hip fracture ≥ 3 % or a 10-year probability of a major osteoporosis-related fracture ≥ 20 % based on the U.S. adapted WHO algorithm (Fracture Risk Algorithm – FRAX®).
4. The member will be concurrently taking a therapeutic dose of vitamin D and calcium documented by chart notes or by prescription claims history.
5. The member has a documented trial and failure, intolerance, or contraindication to two bisphosphonates.

Note: Formulary bisphosphonates include alendronate tablets, ibandronate tablets, or zoledronic acid (Reclast intravenous injection). Prior authorization required for zoledronic acid.
- Contraindication may be defined as severe renal impairment of CrCl < 35 mL/min, evidence of acute renal impairment, or if hypocalcemia present.
- Intolerance to oral bisphosphonates may be defined as having a documented pre-existing gastrointestinal disorder such as Barrett’s esophagus, dysphagia, active ulcer or duodenitis, or other esophageal diseases
- Failure defined as lack of improvement in T-score after an adequate treatment duration of at least 1 year

6. The member has a documented trial and failure of denosumab (Prolia) per medical claims or a contraindication to Prolia.
   - Failure defined as lack of improvement in T-score after an adequate treatment duration of at least 1 year
   Note: Prolia requires prior authorization.

7. The member has a documented trial and failure of per chart notes or prescription claim history, or contraindication to Tymlos for the diagnosis of postmenopausal osteoporosis in women who are at high risk of fracture.
   - Failure defined as lack of improvement in T-score after an adequate treatment duration of at least 1 year

8. The member will not be receiving concomitant bisphosphonate, SERM, or Prolia therapy with Forteo.
9. The total duration of treatment with Forteo and/or with Tymlos will not and has not exceeded two years.

**Tymlos** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by or in consultation with a rheumatologist or endocrinologist.
2. The member has one of the following diagnoses:
   a. Postmenopausal osteoporosis in women who are at high risk of fracture
3. Osteoporosis diagnosis is supported by submitted documentation of one of the following:
   a. A current hip or vertebral fracture that is clinically apparent or found upon vertebral imaging.
   b. A T-score ≤ −2.5 at the femoral neck, total hip, or lumbar spine dated within the past 12 months.
   c. Low bone mass (T-score between −1.0 and −2.5 at the femoral neck or lumbar spine) and a 10-year probability of a hip fracture ≥ 3 % or a 10-year probability of a major osteoporosis-related fracture ≥20 % based on the US adapted WHO algorithm (Fracture Risk Algorithm – FRAX®).
4. The member will be concurrently taking a therapeutic dose of vitamin D and calcium documented by chart notes or by prescription claims history.
5. The member has a documented trial and failure, intolerance, or contraindication to two bisphosphonates.

Note: Formulary bisphosphonates include alendronate tablets, ibandronate tablets, or zoledronic acid (Reclast intravenous injection). Prior authorization required for zoledronic acid.
• Contraindication may be defined as severe renal impairment of CrCl < 35 mL/min, evidence of acute renal impairment, or if hypocalcemia present.
• Intolerance to oral bisphosphonates may be defined as having a documented pre-existing gastrointestinal disorder such as Barrett’s esophagus, dysphagia, active ulcer or duodenitis, or other esophageal diseases
• Failure defined as lack of improvement in T-score after an adequate treatment duration of at least 1 year

6. The member has a documented trial and failure of Prolia per medical claims or a contraindication to Prolia.
   • Failure defined as lack of improvement in T-score after an adequate treatment duration of at least 1 year
   Note: Prolia requires prior authorization.

7. The member will not be receiving concomitant bisphosphonate, SERM, or Prolia therapy with Tymlos.
8. Total duration of treatment with Forteo and/or with Tymlos will not and has not exceeded two years.

Approval Length: 12 months
Quantity Limits: One pen per 28 days.

Continuation Criteria:
1. Documentation submitted supports an increase in BMD evidenced by T-score improvement from baseline in lumbar spine, femoral neck or total hip.

Exclusions:
1. Use of Forteo or Tymlos for a cumulative total duration of either product for more than 24 months during a patient’s lifetime.
2. Use of Forteo or Tymlos for prevention of osteoporosis.
3. Use of Forteo or Tymlos in patients with bone metastases, history of skeletal malignancies, hypercalcemic disorders, or for metabolic bone diseases other than osteoporosis.
4. Administration by a health care professional. Forteo and Tymlos are considered self-injectable products.

References:
Criteria effective 10/01/2018; Last reviewed March 2019
**Criteria Name**
Continuous Glucose Monitor – Freestyle Libre

**CRITERIA FOR COVERAGE/NONCOVERAGE**

FreeStyle Libre and FreeStyle Libre 14 day Flash Glucose Monitoring systems are continuous glucose monitoring (CGM) devices indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. This system does not alarm for hypoglycemia or hyperglycemia in comparison to other CGM systems. Fingerstick glucose levels are required to confirm hypoglycemia or pending hypoglycemia.

***Note: Freestyle Libre is approved for use in patients 18 and older. Dexcom may be used in patients 2 and older.***

FreeStyle Libre 14 day will be considered for coverage when the following criteria are met:

a. The member has diabetes mellitus (Type 1 or Type 2); and  
b. The member is 18 years of age or older; and  
c. The member has been using a blood glucose monitor (BGM) and performing frequent (four or more times a day) testing; and  
d. The member is insulin-treated with multiple (three or more) daily injections of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and  
e. The member’s insulin treatment regimen requires frequent adjustment by the member on the basis of BGM or CGM testing results; and  
f. The member does not have episodes of hypoglycemic unawareness or nocturnal hypoglycemia as evidenced by two episodes over a two week period.

Limitations and Exclusions:

3. FreeStyle Libre readers and sensors must be dispensed through an in-network pharmacy.  
   - Requests for coverage through a DME vendor must be redirected to an in-network pharmacy.  
4. Members under the age of 18 will be reviewed on a case by case basis by a Plan Medical Director.  
5. Quantity Limit of 2 per 28 days

Approval Duration: 12 months

Last revised: 5/2019
**Brand Name** | **Generic Name**
---|---
FUZEON | enfuvirtide

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**FUZEON/enfuvirtide** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member must be clinically diagnosed with HIV-1 infection and meet all criteria below:

1. At least 5 log (10) copies of HIV-1 RNA per ml of plasma

2. Tried/failed/intolerance to ≥ 3 classes of anti-HIV therapy (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, and protease inhibitor) after 3 or more months of therapy.

3. Member will use Fuzeon in combination with other antiretroviral agents.

Authorization for continued use shall be reviewed at least every 3 months to confirm there are no contraindications to therapy.

References
   Criteria last reviewed and updated: March 2019
**Covered products** | **Brand or generic Name**
---|---
Galantamine oral tablets | RAZADYNE
Galantamine oral solution | RAZADYNE
Galantamine capsules controlled release (CR) | RAZADYNE ER

**CRITERIA FOR COVERAGE/NONCOVERAGE**

*Galantamine* is a cholinesterase inhibitor indicated for the treatment of mild to moderate dementia of the Alzheimer’s type.

Galantamine tablets and oral solution should be administered twice a day.

Galantamine controlled released capsules should be administered once daily in the morning.

*Galantamine tablets, CR capsules, or oral solution* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member must be 18 years old or older.
2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.
3. Documented diagnosis of mild to moderate dementia associated with Alzheimer’s disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
   a. Between 20 – 24 points for mild disease.
   b. Between 13 – 20 points for moderate disease.

**OR**

Documented diagnosis of multi-infarct (vascular) dementia and brain imaging confirms evidence of cerebrovascular disease (CVD). Cognitive screening test results such as MMSE, mini-cog, 7 minute screen, Montreal Cognitive Assessment (MOCA) or SLUMS must be included.

**Quantity Limits:**

Galantamine tablets – Up to #60 per 30 days
Galantamine oral solution – 180 ml per 30 days
Galantamine CR capsules – Up to #60 per 30 days

**Length of Approval:** Three months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

**Continuation Criteria:**

1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score for dementia related to Alzheimer’s Disease.
2. Documentation member is receiving a positive clinical response evidenced by an improvement in cognitive testing for vascular dementia.

**Exclusions:**

1. Not for use for other non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.

**References:**

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**BYETTA, BYDUREON, or VICTOZA** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member must meet the following criteria for initial authorization:

1. Baseline A1c or goals of therapy

2. The member has a diagnosis of Type 2 Diabetes Mellitus (DMII) and has established atherosclerotic cardiovascular disease (ASCVD) (cardiovascular death, non-fatal MI or stroke)
   - Failure to obtain adequate glycemic control (A1c) after at least a 2 months (60 days) trial of maximum tolerated dose of metformin
     OR
   - Member is unable to take metformin due to intolerance (defined as ongoing GI problems (diarrhea, nausea, abdominal cramping) OR has contraindication (e.g., eGFR below 30mL/min).

3. The member has a diagnosis of Type 2 Diabetes Mellitus (DMII) and no cardiovascular disease
   - Failure to obtain adequate glycemic control (A1c) after at least a 2 months (60 days) trial of metformin and ONE additional diabetic agent (e.g., sulfonylureas (SU), dipeptidyl peptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 (GLP-1) agonists, insulin, pioglitazone) OR metformin in combination of Insulin; OR another diabetic regimen if member is unable to take metformin due to intolerance (defined as ongoing GI problems (diarrhea, nausea, abdominal cramping) OR has contraindication (e.g., eGFR below 30mL/min).

4. Requested medication will not be used in combination with a DPP-4 inhibitor (e.g., Januvia [sitagliptin], Tradjenta [linagliptin], Onglyza [saxagliptin]).

   *Note: The American Diabetes Association (ADA) 2019 standards of medical care in diabetes do not recommend the use of GLP-1 receptor agonists in combination with DPP-4 inhibitors due to lack of or insufficient data regarding their combined use.*

**Symlin**

Member must meet the following criteria for initial authorization:

1. The member has diagnosis of Type 1 or type 2 diabetes mellitus
2. Failure to obtain adequate glycemic control despite 3 months (90 days) or more of daily mealtime insulin therapy

Initial approval duration: 6 months

Criteria for continuation:

1. Member had improvement in target goals (e.g., a reduction in hemoglobin A1C, glucose level, weight loss) since starting this therapy (3-6 months) and does not have adverse effects or contraindications.

Continuation approval duration: 12 months

Exclusion to therapy:

- Saxenda (liraglutide) injections for weight management is benefit exclusion
- Pre-diabetic patients (e.g., HbA1c ≥ 5.7% and FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L) OR HbA1c <5.7%).
- Byetta, Bydureon, Victoza: Patient with personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- Symlin: Patients with diagnosis of gastroparesis or taking drugs that alter gastrointestinal motility or drugs that slow intestinal absorption of nutrients (e.g., erythromycin, metoclopramide, cholestyramine, Colestid, Welchol, Donnatal, Lomotil, Precose).

References

Criteria last updated September 2019
**Brand Name – AHCCCS Preferred Product** | **Generic Name**
--- | ---
GLYXAMBI | empagliflozin/linagliptin

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Glyxambi** is a combination of empagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor and linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate.

**Glyxambi** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Baseline A1c or goals of therapy
2. The member has a documented diagnosis of Type 2 Diabetes Mellitus (DMII) and established atherosclerotic cardiovascular disease (ASCVD).
   - Failure to obtain adequate glycemic control (A1c) after at least a 2 months (60 days) trial of maximum tolerated dose of metformin
     OR
   - Member is unable to take metformin due to intolerance (defined as ongoing GI problems (diarrhea, nausea, abdominal cramping) OR has contraindication (e.g., eGFR below 30mL/min).
3. Member has diagnosis of type 2 Diabetes Mellitus (DMII) and no cardiovascular disease
   - Failure to obtain adequate glycemic control (A1c) after at least a 2 months (60 days) trial of metformin and ONE additional diabetic agent (e.g., sulfonylureas (SU), dipeptidyl peptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 (GLP-1) agonists, insulin, pioglitazone) OR metformin in combination of Insulin; OR another diabetic regimen if member is unable to take metformin due to intolerance (defined as ongoing GI problems (diarrhea, nausea, abdominal cramping) OR has contraindication (e.g., eGFR below 30mL/min).
4. eGFR ≥ 30-59mL/min.

**Initial approval duration: 6 months**

**Continuation Criteria:**
Member had improvement in target goals (a reduction in hemoglobin A1C, glucose level) since starting this therapy (3-6 months) does not have adverse effects or contraindications.

**Continuation approval duration: 12 months**
Exclusions:

- Pre-diabetic patients (e.g., HbA1c ≥ 5.7% and FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L) OR HbA1c <5.7%).

References:


Criteria last reviewed/updated: March 2019
GRALISE | Gabapentin extended-release tablets

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Gralise** is indicated for the management of post-herpetic neuralgia (PHN). It is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.

Gralise should be titrated up to a therapeutic dose of 1800 mg taken orally once a day. Available as a 300 mg and 600 mg tablet.

Gralise will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Diagnosis of post-herpetic neuralgia (PHN).
2. Must be 18 years old or older.
3. Member had trial and failure of (up to 90 days) or intolerance to both of the following:
   a. Gabapentin (generic Neurontin) up to 1,800mg per day OR Lyrica (pregabalin) up to 150-600mg per day (Prior authorization required) for at least 90 days.
   b. Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, desipramine)

Exclusion criteria:

1. Gralise should not be used in patients with CrCl less than 30 or patients on hemodialysis

*Internal Rph note:*

- Avoid TCA in patients with heart disease, epilepsy or glaucoma and should be used cautiously in older patients.

**Quantity Limits:** Up to #90 per 30 days for either strength.

**Length of Approval:** 12 months

**Continuation Criteria:**

1. Documentation member is receiving a positive clinical response to Gralise based upon reevaluation in the past 12 months.
References:


Criteria created 9/2017; revised 06/2019.
GROWTH HORMONE/somatropin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Preferred Products - GENTROPIN and NORDITROPIN are required prior to requests for non-preferred growth hormones, unless there is a documented intolerance or documented hypersensitivity to ALL preferred products. All preferred products must be considered prior to non-preferred products. An exception will be granted to the use of SEROSTIM and ZORBTIVE, when SEROSTIM or ZORBTIVE are prescribed for their FDA-approved uses.

Pediatric Uses: Children < 18 years of age: Criteria for initial authorization (12 months)

A. Documentation of open epiphyses for members > 12 years of age
B. Member does not have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
C. Member does not have an active malignancy
D. Member does not have active proliferative or severe non-proliferative diabetic retinopathy
E. The prescription is written by or in consultation with a pediatric endocrinologist
F. The member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Growth hormone deficiency (GHD) and both the following criteria are met (i) and (ii):
   i. One pharmacological GH stimulation test result with peak GH secretion <10 ng/ml or IGF-1/IGFBP3 level more than 2 SDS below the mean if member with defined CNS pathology, history of irradiation, or proven genetic cause (acceptable tests include: arginine, clonidine, glucagon, exercise, insulin- induced hypoglycemia, levodopa)
   ii. Member meets one of the height standard deviation score or growth velocity criteria below:
      a) Height SDS more than 3 SDS below the mean for chronological age and sex
b) Height SDS more than 2 SDS below the mean for chronological age and sex and decreased growth velocity more than 1 SDS below the mean for chronological age and sex

c) GV measured over one year 2 SDS below the mean for chronological age and sex

2. **Small for gestational age (SGA)** and the following criteria are met:
   i. Age is > 2 years
   ii. Child was born SGA, defined as birth weight or length two or more SDs below the mean for gestational age
   iii. Child fails to manifest catch up growth by age two years, defined as height two or more SDs below the mean for age and sex.

3. **Chronic renal insufficiency** and the following criteria are met:
   i. Child’s nutritional status has been optimized and metabolic abnormalities have been corrected
   ii. Member has not had a kidney transplant
   iii. Height < 3rd percentile or a GV measured over 1 year > 2 SD below the mean for chronological age and sex.

4. **Short Stature Homeobox-containing Gene (SHOX) Deficiency or Noonan Syndrome** and one of the following criteria are met:
   i. Height SDS more than 3 SDS below the mean for chronological age and sex
   ii. Height SDS more than 2 SDS below the mean for chronological age and sex and decreased growth velocity more than 1 SDS below the mean for chronological age and sex
   iii. GV measured over one year 2 SDS below the mean for chronological age and sex

5. **Prader-Willi syndrome** and the following criteria are met:
   i. The diagnosis of Prader-Willi syndrome is confirmed by appropriate genetic testing
   ii. Member does not have any of the following exclusions to therapy: severe obesity, history of upper airway obstruction or sleep apnea, or severe respiratory impairment
   iii. Height SDS more than 2 SDS below the mean for chronological age and sex.

6. **Turner’s syndrome** and the following criteria are met:
   i. The diagnosis of Turner's syndrome is confirmed by chromosome analysis
   ii. Height < 5th percentile for chronological age and sex.

**Criteria for renewal for Pediatrics**: Authorization for continued use shall be reviewed every 12 months to confirm that any of the following criteria are met:

1. Member continues to meet safety criteria
2. Member’s epiphyses are open
3. Member is being monitored for therapy response and meet one of the following criteria:
a. Final adult height has not been reached as determined by the fifth percentile of adult height
b. GV is >2 cm/year

**Growth Hormone for Adult Uses: Members ≥ 18 years of age:** Criteria for initial authorization (12 months)

A. The prescription is written by or in consultation with an endocrinologist
B. GH treatment must be discontinued for at least one month if previously treated with somatropin for GHD in childhood
   1. Member should have a subnormal IGF-1 (after at least one month off of GH therapy in members previously receiving GH therapy)
C. Member does not have any of the following exclusions to therapy:
   1. Active proliferative or severe non-proliferative diabetic retinopathy
   2. acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
   3. Active malignancy
D. Member must have one of the following diagnoses:
   1. Childhood or adult-onset GHD confirmed or reconfirmed by subnormal response to two standard GH stimulation tests (assay type must be provided):
      i. At least one test must be the insulin tolerance test (ITT) with documented blood glucose nadir of <40 mg/dL (<2.2mmol/L); If ITT is contraindicated (which must be documented), then a standardized stimulation test as noted below
      ii. Subnormal GH is assay dependent and defined as:

<table>
<thead>
<tr>
<th>Test</th>
<th>PeakGH</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT</td>
<td>≤5 ng/ml</td>
<td>N/A</td>
</tr>
<tr>
<td>Arginine</td>
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<td>Glucagon</td>
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<td>Arginine+</td>
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<td>&lt;25 kg/m²</td>
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<tr>
<td>GHRH</td>
<td>≤8 ng/ml</td>
<td>≥25 and &lt;30 kg/m²</td>
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<tr>
<td></td>
<td>≤4 ng/ml</td>
<td>≥30 kg/m²</td>
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</tbody>
</table>

2. GHD with at least one additional pituitary hormone deficiency confirmed by a subnormal response to at least one GH stimulation test (ITT is test of choice unless contraindication, which must be documented [see above for peak GH level requirements])
3. GHD with panhypopituitarism (three or more documented pituitary hormone deficiencies)
4. GHD with irreversible hypothalamic-pituitary structural lesions as a result of tumors, surgery, radiation, head trauma, subarachnoid hemorrhage of the pituitary or hypothalamic region

E. Member must have clinical features associated with GH deficiency (e.g. increased abdominal fat mass, low bone density as measured by BMD T-score, elevated blood pressure, elevated LDL or total cholesterol and low HDL, decreased muscle mass and strength).

**Growth Hormone for Adult Uses: Members ≥ 18 years of age:** Criteria for renewal authorization (12 months)
Authorization for continued use shall be reviewed every 12 months to confirm that any of the following criteria are met:

1. Member has experienced an improvement of normalization of IGF-1 levels (not a requirement for adults with panhypopituitarism)
2. Member continues to meet safety criteria

**ZORBIVTE** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a diagnosis of short bowel syndrome
2. Member is receiving specialized nutritional support (i.e. parenteral nutrition)
3. Member does not have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
4. Member does not have an active malignancy
5. Member does not have active proliferative or severe non-proliferative diabetic retinopathy

**Duration of approval is limited to 4 weeks. Additional authorizations not provided.**

**SEROSTIM** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a diagnosis of AIDS-wasting syndrome or cachexia (defined as unintentional weight loss ≥ 10% of baseline weight)
2. Member has a documented trial and failure or intolerance to dronabinol or megestrol
3. Member is currently receiving treatment with antiretrovirals
4. Member does not have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
5. Member does not have an active malignancy
6. Member does not have active proliferative or severe non-proliferative diabetic retinopathy

**Initial authorization (duration limited to 12 weeks)**

**Renewal authorization (duration limited to 12 weeks) and member must meet the following criteria:**

- Member has experienced an increase in body weight and/or improvement in lean body mass
- Wasting is still evident
- Member continues to meet safety criteria
Serostim is considered experimental/investigational for conditions not listed in this coverage policy section.

References
Criteria last reviewed and updated: 3/2019
Hemlibra is a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

Hemlibra will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by a hematologist.
2. Diagnosis of congenital factor VIII deficiency confirmed by blood coagulation testing, and using for routine prophylaxis of bleeding episodes.
3. Documentation of member’s weight within the past 30 days and confirmation of appropriate dosing.

For treatment of Hemophilia A with factor VIII inhibitors:
3. Lab documentation submitted confirming a high anti-FVIII titer (> 5 Bethesda units/mL).
4. Documentation submitted supporting one of the following:
   a) Member has at least two documented episodes of spontaneous bleeding into joints in the past 6 months
   b) Member has documented trial and failure of or is currently on routine prophylaxis with a activated prothrombin complex concentrate (aPCC) product or “bypassing agent” (i.e. NovoSeven, FEIBA)
5. Will not be used in combination with an aPCC product or “bypassing agent” such as NovoSeven, FEIBA, or similar other products.
6. Will not be used in combination with Immune Tolerance Induction (ITI).

For treatment of Hemophilia A without factor VIII inhibitors:
1. Documentation member has tried and failed, or is unable to use formulary long-acting alternatives; and/or necessity of subcutaneous administration over infusion.

Approval Length: Three months initially then up to 12 months thereafter based on clinical response.
Quantity Limits: Quantity approvable is based on dosing of 3 mg/kg once a week for the first 4 weeks and then 1.5mg/kg once a week, 3mg/kg once every 2 weeks, or 6mg/kg every 4 weeks, thereafter.
Continuation Criteria:
1. Documentation of member’s weight within the past 30 days is submitted and the requested dosing is consistent with current weight and the appropriate vial size is utilized.
3. Documentation submitted supporting member is receiving positive clinical response with therapy
5. Adherence to Hemlibra is supported by prescription claims history and/or documentation submitted.
6. Any cumulative amount of medication(s) the member has on-hand will be taken into account when reauthorizing.

Exclusions:
1. Requests for Hemlibra with doses greater than prescribed for the given weight to allow for waste or overfill to occur.

**If all criteria met and approval is granted, medication will ONLY be dispensed by a AHCCCS defined specialty pharmacy vendor (currently CVS Health) at the discretion of Health Choice**

References:
2. ICER. Institute for Clinical and Economic Review posts draft scoping document to guide review of emicizumab for hemophilia A.

Criteria last reviewed/updated: March 2019
<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Brand name</th>
</tr>
</thead>
<tbody>
<tr>
<td>entecavir tablets, solution</td>
<td>BARACLUDE</td>
</tr>
<tr>
<td>adefovir dipivoxil tablets</td>
<td>HEPSPERA</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

Entecavir (Baraclude) is a hepatitis B virus nucleoside analogue reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection in adults and children at least 2 years of age with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Adefovir (Hepsera) is a nucleotide analogue indicated for the treatment of chronic hepatitis B in patients 12 years of age and older.

**Entecavir and adefovir** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member is 2 years of age or older for entecavir, 12 years of age or older for adefovir.
2. Must be prescribed by, or in consult with an infectious disease physician, a gastroenterologist, a hepatologist, or a transplant physician.
3. Member has a documented diagnosis of chronic hepatitis B. Chronic defined as the initial presence of the HBsAg for at least 6 months or more.
4. If the documentation submitted supports a patient diagnosis of chronic hepatitis B with **no cirrhosis** then the following laboratory documentation are required:
   a. For HBeAg-positive patients, serum HBV DNA > 20,000 IU/mL and alanine transaminase (ALT) is > 2 x upper limit of normal (ULN).
   b. For HBeAg negative patients, serum HBV DNA > 2,000 IU/mL and ALT is > 2 x ULN.

**Note:**  *ULN defined as 30 U/L for males and 19 U/L for females.*

**Note:** *Members with a diagnosis of chronic hepatitis B infection can initiate hepatitis B antiviral therapy regardless of HBeAg status or serum ALT levels if any of the following apply:*

- Acute liver failure
- Decompensated cirrhosis
- Compensated cirrhosis
A liver transplant recipient
A solid organ transplant recipient from a hepatitis B positive donor

Continuation criteria for members with chronic hepatitis B infection and no cirrhosis:

- HBeAg positive members – approval is continued at every 3 month intervals until ALL of the following is met:
  - Loss of HBeAg
  - Undetectable serum HBV DNA
  - Has completed 6 to 12 months of additional treatment after appearance of anti-HBe
- HBeAg negative members – approval is continued at every 3 month intervals until loss of HBsAg.

Continuation criteria for members with chronic hepatitis B infection and cirrhosis:

- Confirmation per chart notes submitted and/or prescription claims history that adherence to medication or regimen is occurring.

Note: Continuation is life-long even if member has sero-converted and/or has had resolution of cirrhosis complications with treatment.

Approval length: Twelve (12) months for all diagnoses except for members with no cirrhosis present. If no cirrhosis present then approval length is every 3 months.

References:

Mavyret is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A).

Mavyret is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Mavyret is available in a tablet form and the recommended dose is three tablets taken once daily with food.

### Approvable Treatment Regimens and Durations:

<table>
<thead>
<tr>
<th>Treatment Naïve or PRS experienced*</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype</td>
<td>No Cirrhosis</td>
</tr>
<tr>
<td>1, 2, 3, 4, 5, or 6</td>
<td>8 weeks</td>
</tr>
</tbody>
</table>

*Treatment experienced to pegylated interferon, ribavirin, or sofosbuvir (PRS)

<table>
<thead>
<tr>
<th>Treatment Experienced</th>
<th>Previously treated with:</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype</td>
<td>Regimen</td>
<td>No Cirrhosis</td>
</tr>
<tr>
<td>1</td>
<td>NS5A inhibitor without NS3/4A</td>
<td>16 weeks</td>
</tr>
<tr>
<td>1</td>
<td>NS3/4A PI without NS5A inhibitor</td>
<td>12 weeks</td>
</tr>
<tr>
<td>1, 2, 4, 5 or 6</td>
<td>PRS*</td>
<td>8 weeks</td>
</tr>
<tr>
<td>3</td>
<td>PRS*</td>
<td>16 weeks</td>
</tr>
</tbody>
</table>

*Treatment experienced to pegylated interferon, ribavirin, or sofosbuvir (PRS)

NS5A inhibitors include: ledipasvir, sofosbuvir, daclatasvir

NS3/4A protease inhibitors include: simeprevir, boceprevir, telaprevir
Mavyret tablets will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.

2. Member is ≥ 12 years old OR weighs ≥ 45kg

3. Diagnosis of chronic hepatitis C infection confirmed by documentation of all of the below:
   a. Detectable serum HCV RNA by quantitative assay (HCV viral load) completed within the past 90 days from the date of the prior authorization request
   b. HCV genotype
   c. Viral resistance status (when applicable)

4. Documentation submitted patient readiness has been assessed and patient attestation of compliance and willingness to participate in a treatment adherence program and is on file in the member’s medical record.

5. Documentation the member agrees to the following:
   a. To complete the treatment regimen
   b. To commit to the anticipated laboratory and imaging tests, and prescribing provider visits.
   c. Understands the risks of reinfection and other contributors to liver disease and/or damage, through a signed attestation.

6. The prescribing clinician agrees by documentation to maintain HCV RNA levels obtained at 12 & 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR).

7. Documentation the member has been screened for Hepatitis A and B and must have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity.

8. Documentation the prescriber will be monitoring hemoglobin levels periodically if a member is prescribed ribavirin.

9. Prescriber has submitted the following laboratory results which have been completed within the last 90 days:
   a. Total bilirubin, albumin, and INR
   b. Creatinine clearance or GFR
   c. LFTs
   d. CBC

10. If Retreatment and the member has history of prior treatment with a direct acting antiviral (DAA), the following documentation is also required:
    a. HCV treatment history including date, drug, dosing, duration and days of therapy completed and responses including SVRs throughout and after previous DAA therapy.
b. **Member was adherent to previous DAA therapy** as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record must be provided which documents these adverse effects and recommendation of discontinuation by treatment provider.

c. **Resistance-associated polymorphism testing**, when applicable, has been completed and submitted with the prior authorization request for regimens that the FDA requires testing prior to treatment to ensure clinical appropriateness; and deemed medically necessary by the clinical reviewer prior to approval of the requested regimen.

d. **Member commits to the documented planned course of treatment** including anticipated laboratory and imaging tests, and prescribing provider visits.

**AND**

13. **Hepatitis C retreatment will not be approved** when:

a. More than one retreatment with a DAA is requested. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA.

b. Documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures exists.

**Exclusions:**

1. DAA dosages greater than the FDA approved maximum dosage.

2. When there is documented non-adherence by a member to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures.

3. Member life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy.

4. Members currently using a potent P-gp inducer drug (St. John’s wort, rifampin, carbamazepine, ritonavir, tipranavir, etc.).

5. Greater than one DAA drug regimen used for retreatment.

6. Based on current evidence, more than one retreatment with a DAA and treatment regimens that include more that one DAA are considered experimental and will not be approved.

7. Lost or stolen medication absent of good cause.

8. Fraudulent use of HCV medications.

**Quantity Limit:** Three tablets per day.
Non-Formulary Hepatitis C medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.

AND

2. Member must have a documented contraindication to a formulary hepatitis C medication or a comorbid medical condition present that a formulary hepatitis C medication is not considered clinically appropriate.
   Examples of acceptable contraindications or medical conditions (not all inclusive):
   a. Member is stabilized on Reyataz (atazanavir)
   b. Member is stabilized on Atripla (efavirenz/emtricitabine/tenofovir)
   c. Member is stabilized on carbamazepine for seizure disorder
   d. Member is less than 18 years of age (see Appendix A for preferred approvable hepatitis C regimens for this age group)

AND

3. The request has been submitted for an approvable Non-Formulary hepatitis C medication regimen.
   Note: See Appendix A for list of the preferred non-formulary approvable Hepatitis C medications, and if all criteria is met.

AND

4. Member is ≥ 18 years old. Note: See Appendix A for list of preferred approvable hepatitis C regimens for members aged 12 to 17 years old and if all criteria is met.

AND

5. Diagnosis of chronic hepatitis C infection confirmed by documentation of all of the below:
   d. Detectable serum hepatitis C virus (HCV) RNA by quantitative assay (HCV viral load) completed within the past 90 days from the date of the prior authorization request
   e. HCV genotype
   f. Viral resistance status when applicable (e.g., NS5A resistance polymorphism testing has been submitted for a request for Zepatier (elbasvir and grazoprevir) for a genotype 1a member)

AND
6. Submitted documentation states that patient readiness has been assessed and patient attestation of compliance and willingness to participate in a treatment adherence program and is on file in the member’s medical record.

AND

7. Documentation the member agrees to the following:
   a. To complete the treatment regimen.
   b. To the anticipated laboratory and imaging tests, and prescribing provider visits.
   c. Understands the risks of reinfection and other contributors to liver disease and/or damage, through a signed attestation.

AND

8. The prescribing clinician agrees by documentation to maintain HCV RNA levels obtained at completion of 12 weeks of therapy and at completion of 24 weeks post therapy to demonstrate the Sustained Virologic Response (SVR).

AND

9. Documentation the member has been screened for Hepatitis A and B and must have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity.

AND

AND

10. If ribavirin is part of the expected hepatitis C regimen (see Appendix A) one of the following:
    1. Documentation the prescriber will be monitoring hemoglobin levels periodically if a member is prescribed ribavirin OR
    2. Member has ribavirin ineligibility or intolerance defined as meeting one or more of the following criteria:
       I. Neutrophils < 750 cells/mm³, results within the past month
       II. Hemoglobin < 10 g/dL, results within the past month
       III. Platelets < 50,000 cells/mm³, results within the past month
       IV. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by ribavirin

AND

13. Prescriber has submitted the following laboratory results which have been completed within the last 90 days:
    a. Total bilirubin, albumin, and international normalized ratio (INR)
    b. Creatinine clearance or glomerular filtration rate (GFR)
    c. Liver Function Tests (LFTs)
    d. Complete blood count (CBC)

AND
14. **If Retreatment and** member has history of prior treatment with a direct acting antiviral (DAA), the following documentation is also required:
   a) **HCV treatment history** including date, drug, dosing, duration, days of therapy completed, and responses including SVRs throughout and after previous DAA therapy.
   b) **Member was adherent to previous DAA therapy** as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record must be provided which documents these adverse effects and recommendation of discontinuation by treatment provider.
   c) **Resistance-associated polymorphism testing**, when applicable, has been completed and submitted with the prior authorization request for regimens that the FDA requires testing prior to treatment to ensure clinical appropriateness; and deemed medically necessary by the clinical reviewer prior to approval of the requested regimen.
   d) **Member commits to the documented planned course of treatment** including anticipated laboratory and imaging tests, and prescribing provider visits.

**AND**

15. **Hepatitis C retreatment** will not be approved when:
   a. More than one retreatment with a DAA. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA.
   b. Documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures exists.

**Exclusions:**

1. DAA dosages greater than the FDA approved maximum dosage.
2. When there is documented non-adherence by a member to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures.
3. Member’s life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy.
4. Members currently using a potent P-gp inducer drug (St. John’s wort, rifampin, carbamazepine, ritonavir, tipranavir, etc.).
5. Greater than one DAA drug regimen used for retreatment.
6. Based on current evidence, more than one retreatment with a DAA and treatment regimens that include more that one DAA are considered experimental and will not be approved.
7. Lost or stolen medication absent of good cause.
8. Fraudulent use of HCV medications.

**Approval Length:** Approval length dependent on FDA approved prescribing recommendations for duration of therapy based on patient type.
## APPENDIX A: Approvable hepatitis C regimens

### Treatment naïve or treatment experienced with no cirrhosis or compensated cirrhosis

<table>
<thead>
<tr>
<th>Genotype 1</th>
<th>Treatment naïve</th>
<th>Treatment experienced to interferon/ribavirin</th>
<th>Treatment experienced to PI**</th>
<th>Treatment experienced to NS5A***</th>
<th>Treatment experienced to sofosbuvir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Zepatier</td>
<td>Zepatier ± ribavirin</td>
<td>Zepatier/ribavirin</td>
<td>Vosevi</td>
<td>Vosevi</td>
</tr>
<tr>
<td></td>
<td>Harvoni x 8wks*</td>
<td>Viekira XR</td>
<td>Epclusa</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Epclusa</td>
<td>Epclusa</td>
<td>Harvoni/ribavirin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Viekira</td>
<td>Harvoni ± ribavirin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 2</th>
<th>Treatment naïve</th>
<th>Treatment experienced to interferon/ribavirin</th>
<th>Treatment experienced to PI**</th>
<th>Treatment experienced to NS5A***</th>
<th>Treatment experienced to sofosbuvir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Epclusa</td>
<td>Epclusa</td>
<td>N/A</td>
<td>Vosevi</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Treatment naïve</th>
<th>Treatment experienced to interferon/ribavirin</th>
<th>Treatment experienced to PI**</th>
<th>Treatment experienced to NS5A***</th>
<th>Treatment experienced to sofosbuvir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Epclusa</td>
<td>Epclusa</td>
<td>N/A</td>
<td>Vosevi</td>
<td>Vosevi</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 4</th>
<th>Treatment naïve</th>
<th>Treatment experienced to interferon/ribavirin</th>
<th>Treatment experienced to PI**</th>
<th>Treatment experienced to NS5A***</th>
<th>Treatment experienced to sofosbuvir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Zepatier</td>
<td>Zepatier</td>
<td>N/A</td>
<td>Vosevi</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Epclusa</td>
<td>Epclusa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Harvoni</td>
<td>Harvoni</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 5 or 6</th>
<th>Treatment naïve</th>
<th>Treatment experienced to interferon/ribavirin</th>
<th>Treatment experienced to PI**</th>
<th>Treatment experienced to NS5A***</th>
<th>Treatment experienced to sofosbuvir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Epclusa</td>
<td>Epclusa</td>
<td>N/A</td>
<td>Vosevi</td>
<td></td>
</tr>
</tbody>
</table>

*Harvoni for 8 weeks is approvable if member is treatment-naïve, genotype 1, is without cirrhosis and has a pretreatment HCV RNA less than 6 million IU/mL.

**Protease inhibitors (PI) include boceprevir, simeprevir, or telaprevir.

***NS5A inhibitors include ledipasvir, daclatasvir, ombitasvir, elbasvir, and velpatasvir

### Treatment naïve or treatment experienced with Child Pugh score of 7 or greater ( Decompensated cirrhosis)

<table>
<thead>
<tr>
<th>Genotype 1</th>
<th>Treatment naïve or treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Epclusa/ribavirin</td>
</tr>
<tr>
<td></td>
<td>Harvoni/ribavirin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 2</th>
<th>Treatment naïve or treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Epclusa/ribavirin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Treatment naïve or treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Epclusa/ribavirin</td>
</tr>
</tbody>
</table>

### Liver transplant recipients

<table>
<thead>
<tr>
<th>Genotype 1</th>
<th>Treatment naïve or treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Viekira XR/ribavirin*</td>
</tr>
<tr>
<td></td>
<td>Harvoni/ribavirin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 2</th>
<th>Treatment naïve or treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Treatment naïve or treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sovaldi/Daklinza/ribavirin</td>
</tr>
</tbody>
</table>
Genotype 4  |  Epclusa/ribavirin
Genotype 5 or 6  |  -
*If normal hepatic function and Metavir fibrosis score ≤ 2.

Pediatric members (age 12 to 17 and weigh at least 35 kg)

<table>
<thead>
<tr>
<th>Approvable regimens in order of preferred status</th>
<th>No cirrhosis</th>
<th>Compensated cirrhosis (Child-Pugh &lt; 7)</th>
<th>Compensated cirrhosis (Child-Pugh &lt; 7) and treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 24 weeks</td>
</tr>
<tr>
<td>Genotype 4</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 12 weeks</td>
</tr>
<tr>
<td>Genotype 5</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 12 weeks</td>
</tr>
<tr>
<td>Genotype 6</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 12 weeks</td>
<td>Harvoni x 12 weeks</td>
</tr>
</tbody>
</table>

Pediatric members (age 12 to 17 and weigh at least 45 kg)

<table>
<thead>
<tr>
<th>Approvable regimens in order of preferred status</th>
<th>No cirrhosis</th>
<th>Compensated cirrhosis (Child-Pugh &lt; 7)</th>
<th>Compensated cirrhosis (Child-Pugh &lt; 7) and treatment experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 16 weeks</td>
</tr>
<tr>
<td>Genotype 4</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
</tr>
<tr>
<td>Genotype 5</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
</tr>
<tr>
<td>Genotype 6</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 8 weeks</td>
<td>Mavyret x 12 weeks</td>
</tr>
</tbody>
</table>
Hetlioz is a melatonin receptor agonist indicated for the treatment of a circadian rhythm sleep disorder known as “Non 24-Hour Sleep-Wake Disorder” or “Non-24”. It is available as a 20 mg capsule and recommended to be taken once a day prior to bedtime at the same time every night.

Hetlioz will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders (sleep specialist) and is board-certified by the American Board of Sleep Medicine (ABSM).
2. The member is ≥ 18 years of age.
3. Documentation the member is totally blind with no perception of light.
4. A documented diagnosis Non 24-Hour Sleep-Wake Disorder is confirmed by meeting the following:
   a. Assessment by at least one of the following physiologic circadian phase marker tests and the results support the diagnosis.
      i. Measurement of urinary melatonin metabolite excretion levels over time.
      ii. Dim light melatonin onset test (DLMO) measured in blood or saliva.
      iii. Assessment of rhythm of core body temperature.
4. The member meets both of the conditions below.
   a. Received at least 6 months of continuous daily therapy with melatonin under the guidance of a physician who specializes in the treatment of sleep disorders.
   b. The member did not achieve adequate results with melatonin therapy according to the prescribing physician or has a documented intolerance or contraindication to the use of melatonin.

   Note: Adequate results defined as clinically meaningful changes of significant increases in nighttime sleep or decreases in daytime sleep that resulted in a change of entrainment status.

Approval Length: Six months initially. Up to 12 months approval thereafter based on clinical response.

Quantity Limit: Thirty capsules per 30 days.

Continuation Criteria:
1. Documentation the member has achieved adequate results with Hetlioz therapy according to the prescribing physician. Adequate results defined as clinically meaningful changes of significant
increases in nighttime sleep or decreases in daytime sleep that resulted in a change of entrainment status.

**Note:** Entrainment defined as a stable alignment or synchronization of the circadian system or internal biologic clock to external time cues such as the natural dark-light cycle. Non-24hr sleep-wake disorder is associated with a loss of entrainment.

**Exclusions:**

1. Concomitant therapy with Rozerem.
   
   **Note:** The safety and efficacy of concomitant use of Rozerem and Hetlioz has not been studied and it is suspected the adverse events with use of these agents together with a similar mechanism of action may be additive (e.g., central nervous system effects such as somnolence, hepatic impairment).

2. Concomitant therapy with sedative/hypnotic medications or with other medications for insomnia/sleep–related disorders such as benzodiazepines, non-benzodiazepines, chloral hydrate.
   
   **Note:** There is no data to support the safety and efficacy of use of hypnotic medications in patients who are blind with Non-24. Additionally there is no data to support the safety and efficacy of Hetlioz when used with other sedative/hypnotic medications or medications used for insomnia/sleep-related disorders.

3. Severe hepatic impairment.

**References:**


Criteria created 3/2018; last reviewed 5/2019
Horizant is indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults and the management of postherpetic neuralgia (PHN) in adults. It is not interchangeable with other gabapentin products including Gralise. Available as a 300mg and 600mg tablet.

Horizant will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Documented diagnosis of moderate-to-severe primary restless leg syndrome (RLS) and all of the following is met:**
   a. Must be 18 years old or older.
   b. Must have had a documented trial and failure of or intolerance to **ALL** of the following:
      i. Gabapentin (up to 1800mg/day of 90 days trial)
      ii. Pramipexole (up to 0.5mg/day of 90 days trial)
      iii. Ropinirole (up to 4mg/day of 90 days trial).
   c. Baseline International Restless Legs Syndrome (IRLS) Rating Scale score of ≥ 15.

2. **Diagnosis of post-herpetic neuralgia (PHN) and meets all of the following:**
   a. Must be 18 years old or older.
   b. Must have had a documented trial and failure of or intolerance to **both** of the following:
      i. Gabapentin (up to 1,800 mg per day of 90 days trial) OR Lyrica* (pregabalin) (up to 150-600mg per day of 90 days trial)  
         *Prior authorization required
      ii. Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, desipramine)

**Continuation Criteria:**

1. For RLS, a decrease in International Restless Legs Syndrome (IRLS) Rating Scale score from baseline OR positive clinical response based on clinical reevaluation in past 12 months.
2. For PHN, documentation member is receiving a positive clinical response to Horizant based upon reevaluation in the past 12 months.
**Length of Approval for initial/continuation therapy:** 12 months

**Quantity Limits:**

RLS – #30 per 30 days.

PHN – Up to #60 per 30 days.

**References:**


Criteria created 9/2017; Revised 03/2019,
H.P. Acthar Gel is an adrenocorticotropic hormone (ACTH) analogue indicated:
- As monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- For the treatment of exacerbations of multiple sclerosis in adults
- May be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.

H.P. Acthar Gel will be considered for coverage under the pharmacy benefit program when the following criteria are met:
1. Infantile Spasms (West Syndrome)
   a. Member must be less than 24 months of age.
   b. Must be prescribed by a neurologist or specialist with expertise with this drug.
   c. Must be used as monotherapy
   d. Clinical diagnosis of infantile spasms confirmed by electroencephalography with documentation of hypsarrhythmia.
   e. Dosing for infantile spasm is as follows and must be consistent with the documentation submitted:
      - Initial dose: 75 U/m2 intramuscular (IM) twice daily for 2 weeks.
      - After 2 weeks, dose should be tapered according to the following schedule: 30 U/m2 IM in the morning for 3 days; 15 U/m2 IM in the morning for 3 days; 10 U/m2 IM in the morning for 3 days; and 10 U/m2 IM every other morning for 6 days (3 doses).

Although FDA labeling has an indication for the treatment of exacerbations of multiple sclerosis in adults H.P. Acthar Gel is not considered medically necessary for this treatment.

Although FDA labeling suggests that H.P. Acthar may be used in the following conditions, they are not FDA indicated. H.P. Acthar Gel is unproven and not medically necessary for treatment of the following disorders and diseases:
- Rheumatic Disorders: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis
- Collagen Diseases: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome
- Allergic States: Serum sickness
- Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- Respiratory Diseases: Symptomatic sarcoidosis
- Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
**Approval length:** One month

**Continuation criteria:**

1. Member has responded positively to the initial treatment course and the provider has supported with documentation a continued need per recent electroencephalography report.
2. Retreatment limited to one additional four week course. Additional courses after second retreatment will require medical director review.
3. Member is still less than 24 months of age.

**References:**


Humira will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of **moderate to severe** rheumatoid arthritis (RA) per chart notes or prescriber attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Hydroxychloroquine
      iii. Leflunomide
      iv. Sulfasalazine
   f. Dosing requested is 40 mg injected once every other week.
      \textbf{Note:} Humira 40 mg injected once a week (regardless of DMARD use) will not be approved unless the member has a documented trial and failure to Enbrel.

2. **Juvenile Idiopathic Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 2 years and current weight is ≥ 10 kg.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of **moderate to severe** rheumatoid arthritis (RA) with at least five swollen joints and at least three joints with limitation of motion
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated
      i. Methotrexate for at least 30 days
      ii. Oral NSAID for at least 30 days
      iii. Oral corticosteroid for at least 14 days
   f. Dosing interval requested is every other week and the dose requested is consistent with the recommended dosing per the FDA label for Humira.

3. **Plaque Psoriasis**
   a. Prescribed by or in consultation with a dermatologist or rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of **moderate to severe** plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
Note: An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.

e. Documentation member has failed topical therapy for a trial of at least 90 days and includes two of the following verified by prescription claims history:
   x. Calcipotriene (generic for Dovonex) topical preparations
   xi. Medium-to-high potency corticosteroids
   Note: For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
   xii. Tacrolimus 0.1% (prior authorization required) ointment
   xiii. Coal tar preparations such as coal tar shampoo

f. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
   vi. Methotrexate oral tablets
   vii. Cyclosporine oral capsules

Dosing requested is 80 mg for the first dose followed by 40 mg every other week.

4. Psoriatic Arthritis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe psoriatic arthritis (PsA)
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Leflunomide
      viii. Sulfasalazine
   f. Dosing requested is 40 mg injected once every other week.
   Note: Humira 40 mg injected once a week (regardless of DMARD use) will not be approved unless the member has a documented trial and failure to Enbrel.

5. Ankylosing Spondylitis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Documentation submitted member has no latent or active tuberculosis infection.
   c. Age ≥ 18 years old.
   d. Documented diagnosis of ankylosing spondylitis.
   e. Trial and failure, unless intolerant or contraindication, per documentation submitted and per prescription claims history of the following:
      i. Two or more prescription required non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, and for greater than 30 days.
Formulary NSAIDs include: ibuprofen, naproxen, naproxen DR, piroxicam, diclofenac, meloxicam, nabumetone, oxaprozin, indomethacin, indomethacin ER, flurbiprofen, fenoprofen, and etodolac.

Note: Oral NSAIDs are recommended as the first-line drug for ankylosing spondylitis per the 2016 ASAS/EULAR guidelines

f. Dosing requested is 40 mg injected once every other week.

Note: Humira 40 mg injected once a week (regardless of DMARD use) will not be approved unless the member has a documented trial and failure to Enbrel.

6. Crohn’s Disease (pediatric and adult)
   c. Prescribed by or in consultation with a gastroenterologist.
   d. Age ≥ 6 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderately to severely active Crohn’s disease.
   e. Member has failed two of the following therapies verified per prescription claims history, unless supported intolerance or contraindication submitted, for ≥ 3 consecutive months:
      i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
      ii. An oral corticosteroid or controlled ileal release budesonide
      iii. A thiopurine such as azathioprine
      iv. Methotrexate
   f. Initial adult dosing requested is 160 mg for the first dose with 80 mg two weeks later and then a maintenance dose of 40 mg every other week. If pediatric request then dose is based on current weight submitted and follows the FDA labeled dosing for Humira.

7. Ulcerative colitis
   a. Prescribed by or in consultation with a gastroenterologist.
   b. Age ≥ 18 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of moderately to severely active ulcerative colitis.
   e. Member has failed two of the following therapies verified per prescription claims history for ≥ 3 consecutive months, unless supported intolerance or contraindication indicated:
      i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
      ii. An oral corticosteroid or controlled ileal release budesonide
      iii. A thiopurine such as azathioprine
      iv. Methotrexate up to 25 mg once weekly
   f. Initial dosing requested is 160 mg for the first dose with 80 mg two weeks later and then a maintenance dose of 40 mg every other week.

8. Hidradenitis Suppurativa (HS)
   a. Prescribed by or in consultation with a dermatologist.
b. Age ≥ 18 years old.
c. Documentation submitted member has no latent or active tuberculosis infection.

d. Documented moderate to severe HS with Hurley Stage II or III disease.

**Note:** Hurley stages
   I. Abscess formation (single) without sinus tract (tunnel) formation
   II. More than one lesion or area but with limited tunneling
   III. Multiple lesions with more extensive sinus tract formations and scarring and involves an entire area of the body.

e. Member has demonstrated an inadequate response, intolerance or contraindication to, at least three of the following conventional treatment measures:
   i. Local hygiene and ordinary hygiene
   ii. Weight reduction in patients who are obese
   iii. Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate)
   iv. Application of warm compresses with sodium chloride solution or Burow’s solution
   v. Laser hair removal
   vi. Cessation of cigarette smoking
   vii. Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride

g. Initial dosing requested is 160 mg for the first dose with 80 mg two week later and then a maintenance dose of 40 mg every week.

9. **Non-infectious Intermediate, posterior uveitis or panuveitis**
   a. Prescribed by a uveitis specialist such as ophthalmologist or ocular immunologist.
   b. Age ≥ 18 years old.
   c. Documentation of failure to, inadequate response, contraindication, or documented intolerance to at least one immunosuppressive drug such as azathioprine, cyclosporine, or methotrexate.
   d. Documentation of failure to, inadequate response, contraindication or documented intolerance to ophthalmic steroids or cycloplegic mydriatics such as homatropine or atropine.
   e. Dosing requested is 80 mg for the first dose followed by 40 mg every other week.

**Approval Length:** Six months initially for all diagnoses. Up to one year thereafter based on clinical response documented.

**Quantity Limits:**

1. **Crohn’s Disease or Ulcerative Colitis:**
   One starter package containing 6 pens will initially be authorized for a 21-day supply, followed by Humira 40 mg pen or syringe – 2 syringes per 28 days thereafter.

2. **Hidradenitis Suppurativa:**
   Humira Hidradenitis Suppurativa Starter Package – one starter package containing 6 pens will initially be authorized for a 21-day supply, followed by Humira 40 mg pen or syringe – 4 syringes per 28 days thereafter

3. **Pediatric Crohn’s Disease:**
   *Members < 40 kg:* Humira Pediatric Crohn’s Disease Starter Package – one starter package containing 3 syringes will initially be authorized for a 21-day supply, followed by Humira 20 mg syringe – 2 syringes per 28 days thereafter.
Members ≥ 40 kg:
Humira Pediatric Crohn’s Disease Starter Package – one starter package containing 6 syringes will initially be authorized for a 21-day supply, followed by Humira 40 mg pen or syringe – 2 syringes per 28 days thereafter

4. **Ankylosing spondylitis, juvenile idiopathic arthritis, psoriatic arthritis, or rheumatoid arthritis** will be limited to a 28-day supply as follows:
   - Humira 10 mg syringe – 2 syringes per 28 days
   - Humira 20 mg syringe – 2 syringes per 28 days
   - Humira 40 mg pen or syringe – 2 syringes per 28 days

5. **Plaque psoriasis or uveitis**:
   Humira Psoriasis/Uveitis Starter Pack – one starter package containing 4 syringes will initially be authorized for a 28-day supply, followed by
   - Humira 40 mg syringe – 2 syringes per 28 days thereafter

**Continuation Criteria:** Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters. The following diagnoses must demonstrate specifically:

- **Ulcerative Colitis** must have documentation submitted supporting clinical remission by the initial eight weeks of therapy (Day 57). If clinical remission has not occurred by Day 57 then denial of request must occur.

**Exclusions/Limitations:**
1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
2. Concomitant use with other biologic medications is considered experimental and investigational.
3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**Congestive heart failure and the use of TNF inhibitors**
The ACR 2015 Treatment Guidelines for rheumatoid arthritis notes there are no reports of exacerbation of heart failure using non-TNF biologics and the US Food and Drug Administration (FDA) warns against using TNF inhibitors in this population based on worsening of congestive heart failure with TNF inhibitors in the Adverse Event Reporting System database. A TNF inhibitor should only be used if there are no other reasonable options, and then, perhaps, only in compensated heart failure.

**Malignancies and the use of TNF inhibitors**
ACR 2015 Treatment Guidelines for rheumatoid arthritis for previously treated or untreated skin cancer (melanoma or non-melanoma) and for previously treated lymphoproliferative disorders state as a recommendation to not use a TNF inhibitor. For previously treated solid organ malignancy the recommendations for treatment are the same as for patients without this condition.

Previous Serious Infections and the use of TNF inhibitors

Per the ACR 2015 Treatment Guidelines for rheumatoid arthritis there was no consensus for making a recommendations regarding the use of other non-TNF biologics over TNF inhibitors in this setting.

References:


Criteria revised: March 2019
**Brand Name- AHCCCS Preferred Product** | **Generic Name**
---|---
HUMULIN R U-500 insulin | Insulin human injection

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Humulin R U-500 insulin** is a concentrated human insulin indicated to improve glycemic control in adults and children with diabetes mellitus requiring more than 200 units of insulin per day. Its safety and efficacy when used in combination with other insulins has not been determined. Its safety and efficacy when delivered by continuous subcutaneous infusion has not been determined.

**Humulin R U-500 insulin** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The member has diabetes mellitus (type 1 or 2), and documentation has been submitted to support a requirement of more than 200 units of insulin per day.

2. The route of administration is by subcutaneous injection. Use by continuous subcutaneous infusion or by insulin pump is not covered.

3. If the request is for the 20 mL multi-dose U-500 vial, the member must have a concurrent prior authorization request or current prior authorization approval for U-500 insulin syringes.

   **Note:** BD U-500 insulin syringes are the only available syringe that has been approved by the FDA for use with U-500 insulin at this time. They are available only by prescription and cannot be purchased over-the-counter.

**Approvable quantity:** The appropriate quantity per units prescribed should be approved for a 30 day supply in order to prevent waste from occurring. See available formulations below.

   **Example:** 200 units per day of U-500 insulin equals 6,000 units per 30 days, so 4 x 3 mL Kwikpens should be approved.

**Available formulations:**

- **3 mL KwikPen**
  - Each 3 mL KwikPen contains 1,500 units of insulin.
  - Once a KwikPen is opened (used), it must not be refrigerated and must be discarded after 28 days.

- **20 mL multiple dose vial containing 10,000 units of insulin**
  - Once opened (used), it must be discarded after 40 days whether it was refrigerated or stored at room temperature.

**Approval length:** 12 months.

**Continuation criteria:** The member must have been adherent to monthly refill quantities consistent with the number of units prescribed per day.
References:
Criteria last reviewed: March 2019
Ilaris is an interleukin-1β blocker indicated for the treatment of Periodic Fever Syndromes including:

- Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older
- Familial Cold Autoinflammatory Syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients.
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients.
- Familial Mediterranean Fever (FMF) in adult and pediatric patients.
- Active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older

Ilaris will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member must be clinically diagnosed with one of the following conditions:
   - Cryopyrin - Associated Periodic Syndromes (CAPS)
     - Familial Cold Autoinflammatory Syndrome (FCAS)
     - Muckle-Wells Syndrome (MWS)
   - Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
   - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
   - Familial Mediterranean Fever (FMF)
   - Active Systemic Juvenile Idiopathic Arthritis (SJIA)
2. Documentation of a trial and failure of Kineret and/or Arcalyst
3. Documentation of labs within the past 30 days including complete metabolic panel, C-reactive protein, serum amyloid A, and complete blood count
4. Documentation that patient is current with all scheduled vaccinations, including Hepatitis A and Hepatitis B and that patient has been counseled on the risks of serious infections associated with this medication as well as avoiding live vaccines while on Ilaris therapy
5. Documentation of current TB test
6. Documentation patient will be self-injecting and has been counseled on preparation/administration of the product

Approval will be granted for 6 months

Exclusion Criteria:
1. Patient has a current infection or has a history of recurring infections or underlying conditions which may predispose to infection

References

Criteria last updated: 4/2019
**INCREASELEX mecasermin** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by a Pediatric Endocrinologist
2. Member’s age >2 and < 20 years old
3. Member does not have active or suspected neoplasia
4. Documentation of open epiphyses
5. Member has a diagnosis of severe primary insulin-like growth factor deficiency (IGFD) or members with growth hormone gene deletion who have developed neutralizing antibodies to GH as defined by all of the following:
   a. IGF-1 level that is considered “low” (< -2 standard deviations below the mean) based on the lab’s reference range
   b. Lab results within 3 months of initial request,
   c. Height standard deviation score ≤ -3.0,
   d. Normal or elevated growth hormone level, (except for growth hormone (GH) deletion), based on growth hormone stimulation test with peak greater than 10 ng/mL.

6. For indications of secondary IGF-1, must have documentation that the following conditions were ruled out:
   a. Growth Hormone Deficiency
   b. Hypothyroidism
   c. Malnutrition

**Criteria for authorization renewal:**

1. Increase in height velocity > 2.5cm total growth in 1 yr
2. No evidence of epiphyseal closure
3. Member has not met their expected final adult height or targeted height based on min-parental height calculation or current absolute height is <= the 25th percentile (defined as 68 inches in males and 63 inches in females).

**(Authorization is for 12 months**

References
Criteria last reviewed and updated: April 2019
**Ingrezza** is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia. The initial dose is 40 mg once daily. After one week, it is increased to a recommended dose of 80 mg once daily.

**Ingrezza** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Member must be > 18 years old.

2. The diagnosis has been clinically established by, or in consultation with, a neurologist or a psychiatrist.

3. **Ingrezza** is to be used for the treatment of symptomatic, moderate to severe tardive dyskinesia (TD).
   
   Symptomatic, moderate to severe TD is defined as one of the following (a or b):
   
   - a. Documentation within 90 days of member’s baseline score defined with one of the following assessment tools:
     
     i. Abnormal Involuntary Movement Scale (AIMS) with a score of 3 or 4 on item 8 (severity of abnormal movement overall).
     
     ii. Extrapyramidal Symptom Rating Scale (ESRS) score ≥ 4.
   
   - b. Patient has been clinically diagnosed with TD by meeting all DSM-V Criteria (i, ii and iii):
     
     i. Involuntary athetoid or choreiform movements.
     
     ii. History of treatment with a neuroleptic agent (i.e. antipsychotic).
     
     iii. Symptoms lasting longer than 8 weeks.

4. The member must have been prescribed and is currently taking a drug that has tardive dyskinesia as a documented adverse reaction (see Table 1 for a list of drugs).

5. An inadequate treatment response, intolerance or contraindication to both of the following treatments:
   
   - a. Clonazepam trial for three months.
   
   - b. Amantadine trial for at least two months.

6. Documentation the member is not at a significant risk for suicidal or violent behavior and does not have unstable psychiatric symptoms.

7. Documentation of recent (within 90 days) Child-Pugh score and the requested dose is appropriate per the FDA Ingrezza prescribing information. Child Pugh Class B or C (≥ 7) is considered moderate to severe hepatic impairment and the recommended Ingrezza dose is 40 mg once daily.

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**NONFORMULARY**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>INGREZZA</td>
<td>valbenazine</td>
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**CRITERIA FOR COVERAGE/NON-COVERAGE**

---
**Exclusions from coverage:**

1. Dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors such as reserpine or Xenazine (tetrabenazine).
2. Concomitant use of a monoamine oxidase inhibitor (MAOI) such as selegiline, Nardil (phenelzine), tranylcypromine, or Marplan (isocarboxazid).
3. Use as a preventative agent for the development of tardive dyskinesias

**Quantity approvable:** #30 per 30 days of the 40mg or 80mg capsules.

**Approval length:** 3 months initially then 1 year thereafter.

**Continuation criteria:**

1. Documented symptom improvement evidenced in the past 90 days by using ONE of the following scores:
   
   a. AIMS – decrease from baseline by at least 2 points.
   
   b. ESRS – decrease from baseline by at least 4 points.

**Table #1. Medications that can cause TD (Vijayakumar and Jankovic 2016)**

<table>
<thead>
<tr>
<th>Class</th>
<th>Drugs within the class</th>
</tr>
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<tbody>
<tr>
<td>First Generation Anti-psychotics (FGAs)</td>
<td>chlorpromazine</td>
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<tr>
<td></td>
<td>chlorprothixene</td>
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<tr>
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<td>droperidol</td>
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<td>fluphenazine</td>
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<td>flupentixol</td>
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<td>haloperidol</td>
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<td>levomepromazine</td>
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<td>Second Generation Anti-psychotics (SGAs)</td>
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<td>Antiemetics</td>
<td>cisapride</td>
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<td>Calcium Channel Blockers</td>
<td>cinnarizine</td>
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<tr>
<td>Serotonin reuptake/serotonin reuptake inhibitors</td>
<td>duloxetine</td>
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<tr>
<td>Tricyclic antidepressants</td>
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<tr>
<td>Central monoamine oxidase inhibitors</td>
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<tr>
<td>Anti-manic agents</td>
<td>lithium</td>
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References:
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<tr>
<th>Covered Product</th>
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<tr>
<td>PULMOZYME®</td>
<td>Dornasealfa</td>
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<tr>
<td>Bethkis – Preferred product</td>
<td>Tobramycin nebulization</td>
</tr>
<tr>
<td>Kitabis PAK – Preferred product</td>
<td>Tobramycin nebulization</td>
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<tr>
<td>Tobramycin INH – NON Preferred</td>
<td>TOBI® INHALATION  NON Preferred</td>
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<tr>
<td>TOBI POD HALER – NON Preferred</td>
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<tr>
<td>Cayston-Non Preferred</td>
<td>Aztreonam</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Bethkis, Kitabis PAK, Tobramycin solution for inhalation or TOBI PODHALER** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Patient has a diagnosis of cystic fibrosis (CF)
2. Sputum cultures is positive for Pseudomonas aeruginosa
3. Patient is six years of age or older
4. For Tobramycin solution for inhalation, TOBI PODHALER (Non-preferred agents): Patient has tried and failed or has contraindication to Bethkis and Kitabis (prior authorization required).

**PULMOZYME (dornase alfa)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Patient has a diagnosis of cystic fibrosis (CF)
2. Patient is five years of age or older

**Cayston (aztreonam)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Patient has a diagnosis of cystic fibrosis (CF)
2. Sputum culture is positive for Pseudomonas aeruginosa
3. Patient is seven years of age and older
4. Patient meets one of following:
   a. Patient had failure of, intolerance or contraindication to inhaled tobramycin (Bethkis, Kitabis, Tobi Podhaler, tobramycin solution) OR cultures show resistance to tobramycin
   b. Susceptibility result show Cayston is the only inhaled antibiotic sensitive to P aeruginosa

**Quantity limits:**
- Bethkis, Kitabis, tobramycin solution: 600mg/day for 28 days of therapy then 28 days off; 56 ampules per 56 days.
- Tobi podhaler: 224mg/day for 28 days of therapy then 28 days off. One package (224 capsules) per 56 days.
- Pulmozyme: 60 (150ml) per 30 days.
- Cayston: 84 ampules per 56 days (28 days of therapy followed by 28 days off)

Authorization for continued use shall be reviewed at least every 12 months to confirm the following:
- Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations)

References


Criteria last reviewed and updated: 05/2019
**Intron A (interferon alfa-2b injection)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member is 18 years of age or older for all indications except Type B viral hepatitis
2. Member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:
   A. Hairy Cell Leukemia (approval duration is 6 months)
   B. Condylomata Acuminata (genital warts)
      i. Approval duration is 3 weeks
      ii. A second course may be repeated at 12 to 16 weeks if there has been a poor response to the initial 3 weeks treatment course.
   C. AIDS-Related Kaposi’s Sarcoma (approval duration is 16 weeks)
   D. Initial treatment of clinically-aggressive Follicular Lymphoma (approval duration up to 18 months)
      i. The medication will be used concurrently with anthracycline-containing combination chemotherapy.
   E. Malignant Melanoma (approval duration – 48 weeks)
      i. The request for coverage is within 56 days of surgery
      ii. The member is free of disease but at high risk for systemic recurrence.
   F. Chronic hepatitis C with compensated liver disease
      i. Member is receiving combination therapy with ribavirin, unless ribavirin is contraindicated
      ii. Intron-A will NOT be used as part of triple therapy with a protease inhibitor
      iii. Member has a documented clinical reason for not using peginterferon (Pegasys or PegIntron)
      iv. Approval duration 18-24 weeks
         **Note: Interferon-containing regimens are no longer recommended in the HCV treatment guidelines.**
   G. Chronic hepatitis B with compensated liver disease
      i. Documentation supporting evidence of hepatitis B viral replication
      ii. Member has been serum hepatitis B surface antigen (HBsAg)-positive for at least 6 months
      iii. Member has elevated serum ALT
      iv. Member is 1 year of age or older
      v. Approval duration is 16 weeks

**Exclusions:**

1. Uncontrolled depression
2. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon
3. Decompensated liver disease

References
Criteria last reviewed and updated: 5/2019
Itraconazole capsule will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member must meet following criteria for Itraconazole (generic Sporanox) capsules:

1. Member has an invasive, systemic fungal infection (Aspergillosis, Blastomycosis, Histoplasmosis, Coccidioidomycosis, Cryptococcosis, Sporotrichosis, Penicilliosis, Microsporidiosis)  
   OR
2. Member has diagnosis of onychomycosis of the finger nails or toe nails due to dermatophytes (tinea unguium) confirmed by laboratory testing (KOH, fungal culture or nail biopsy)  
   AND  
   Member had a trial and failure of terbinafine tablets (generic Lamisil).  
   OR
3. Member has diagnosis of tinea versicolor or pityriasis AND member had trial and failure of formulary topical antifungal agents. 
   OR
4. Member has diagnosis of Tinea corporis, Tinea cruris, Tinea manuum, Tinea pedis and member had trial and failure of griseofulvin or formulary topical antifungal agents.

Member must meet following criteria for Itraconazole (generic Sporanox) solution:

- Member has diagnosis of oropharyngeal and esophageal candidiasis AND member had trial and failure of fluconazole  
  OR
- Member has an invasive, systemic fungal infection (Aspergillosis, Blastomycosis, Histoplasmosis, Coccidioidomycosis, Cryptococcosis, Sporotrichosis, Penicilliosis, Microsporidiosis)  
  AND  
  Member is unable to swallow itraconazole capsules.

Approval duration:

- Toenail onychomycosis: 12 weeks  
- Fingernail onychomycosis: 5 weeks (2 treatment pulses for 1 week separated by 3 weeks)
• Oropharyngeal and esophageal candidiasis: 4 weeks
• All other conditions: 12 months.

References
Criteria last reviewed and updated: 03/2019.
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>JULUCA</td>
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</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

Juluca, a two-drug combination of dolutegravir, a human immunodeficiency virus type 1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, a HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Juluca.

Juluca will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. A diagnosis of HIV-1 infection.
2. Lab documentation drawn in the last 6 months supporting viral suppression as determined by HIV-1 RNA < 50 copies per mL.
3. Documentation per prescription claims history member has been on a stable antiretroviral regimen for the last 6 months.
4. No known amino acid substitutions associated with resistance to the individual components of Juluca.
5. Documented trial and failure of, or intolerance to, all of the individual drug components in Juluca (dolutegravir – Tivicay and rilpivirine – Edurant).

Approval Length: 12 months.

Quantity Limits: 30 tablets per 30 days.

Continuation Criteria:
1. Member has been adherent to the medication as evidenced by prescription claim history or supported by other documentation.

Exclusions:
1. Concomitant therapy with other antiretroviral medications.
2. Requested use of Juluca is to decrease total pill burden per day.

References:
Criteria effective 7/1/2018; Last reviewed April 2019
### Brand Name | Generic Name  
---|---  
JUXTAPID™ | Lomitapide mesylate  

## CRITERIA FOR COVERAGE/NONCOVERAGE

**JUXTAPID (lomitapide mesylate)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidence by one of the following:
   a. Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR
   b. Untreated/pre-treatment LDL > 500 mg/dL with at least one of the following:
      - Cutaneous or tendinous xanthoma before age 10 years
      - History of early vascular disease (men < 55 years of age, women < 60 years of age) on both sides of the family if parental LDL levels are unknown
      - Elevated LDL cholesterol levels before lipid-lowering therapy consistent with heterozygous FH in both parents where LDL levels are known:
        - LDL cholesterol > 250 mg/dL in a patient aged 30 or more;
        - LDL cholesterol > 220 mg/dL for patients aged 20 to 29;
        - LDL cholesterol > 190 mg/dL in patients under age 20;

2. Juxtapid will be used as adjunct to a low-fat diet and other lipid-lowering treatments

3. Patient does not have any of the following contraindications to therapy:
   a. Pregnancy
   b. Concomitant use with strong or moderate CYP3A4 inhibitors
   c. Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests

4. Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g. atorvastatin, rosuvastatin), unless all statins are contraindicated

**Juxtapid is subject to a quantity limit of 30 tablets every 30 days.**

**Initial authorizations will be granted for 6 months.** Reauthorizations for continued use shall be reviewed yearly. Renewal criteria shall confirm the following:

1. Patient has responded to therapy (i.e. decreased LDL levels) from baseline
2. Patient does not have any contraindications to therapy
References
Criteria last reviewed and updated: 11/2016
Kalydeco is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 6 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. Clinical studies have demonstrated a positive impact on forced expiratory volume (FEV1), pulmonary exacerbations, weight gain, and quality of life. Kalydeco is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene.

Orkambi, a combination of lumacaftor and ivacaftor, is indicated for the treatment of CF in patients age 2 years and older who are homozygous for the F508del mutation in the CFTR gene.

Symdeko, a combination of tezacaftor and ivacaftor, indicated for the treatment of patients with CF aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.

The above medications will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Must be prescribed by, or in consultation with a specialist (e.g., pulmonologist/critical care or a provider with a CF center)
2. Baseline FEV1 ≥ 40% has been submitted.
3. Baseline liver function tests (ALT/AST) has been submitted.
4. If member is age 12 to 17 years of age, baseline ophthalmological exam to monitor for lens opacities/cataracts has been completed. Not required in adults 18 years and older.
   a. **Kalydeco**
      i. Kalydeco granules: Age 6 months to less than 6 years; Kalydeco tablets: Age 6 years and older.


iii. Member is not homozygous for the F508del mutation

b. Orkambi
   i. Member has diagnosis of cystic fibrosis (CF) with F508del homozygous gene mutation confirmed by FDA approved CF mutation test.
   ii. Orkambi granules: Age 2 years or older; Orkambi tablet: Age 6 years and older.

c. Symdeko
   i. Member has diagnosis of cystic fibrosis (CF) with one of the following confirmed by FDA approved CF mutation test:
      2. Member is homozygous for F508del mutation in the CFTR gene
      3. Member is age 12 years or older.

Approval Length: Three months for the first year then 12 months thereafter.
Quantity Limits: Kalydeco – up to 56 tablets or packets per 28 days, Orkambi - 112 tablets per 28 days, Symdeko - 56 tablets per 28 days

Continuation Criteria:
   1. Member is tolerating and responding to the medication and the disease response is supported by one of the following compared to baseline:
      a. Stable or improved FEV1
      b. Weight gain
      c. Decreased exacerbations
   2. Member is adherence to therapy (supported by documentation from chart notes or prescription claim history).
   3. Liver function tests (ALT/AST) submitted with renewal during first year of treatment and annually thereafter and meets both of the below.
      a. ALT or AST does not exceed 5 times the upper limit of normal.
      b. ALT or AST does not exceed 3 times upper limit of normal with bilirubin greater than 2 times upper limit of normal.

References:

Criteria last updated: 6/2019
Kevzara is a self-administered subcutaneous injection of an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

**Kevzara** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) and one or more of the following:
      iii. Clinical Disease Activity Index (CDAI) > 10.0
      iv. Disease Activity Score 28 (DAS) ≥ 3.2
      v. Simplified Disease Activity Index (SDAI) > 11.0
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated:
      i. Methotrexate for ≥ 3 consecutive months
      ii. If documented intolerance or known contraindication to MTX, then one of the following disease-modifying antirheumatic agent for ≥ 3 consecutive months
         • Hydroxychloroquine
         • Sulfasalazine
         • Leflunomide
   f. Prescribed concomitantly with MTX or another agent if intolerance or contraindication to MTX.

   **Note:** Per 2015 ACR (American College of Rheumatology) Treatment Guidelines for rheumatoid arthritis biologic therapy should be used in combination with methotrexate, when possible, due to superior efficacy of this combination over biologic monotherapy.

   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
   h. Recent lab documentation submitted of hepatic function, absolute neutrophil count (ANC), and platelets.
   i. Documentation Kevzara will be self-administered by subcutaneous injection by the member.
Approval Length: Three months initially then up to 12 months thereafter based on clinical response.

Quantity Limits: Two prefilled syringes/pens every 30 days.

Continuation Criteria:
1. Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters by supporting a result of at least one of the following disease activity measurements listed below.
   - Clinical Disease Activity Index (CDAI) < 10.0
   - Disease Activity Score 28 (DAS) ≤ 3.2
   - Simplified Disease Activity Index (SDAI) < 11.0

Exclusions:
1. Concomitant use with other biologic DMARD medications (oral and injectable).
2. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:

Criteria effective: 10/01/2018

Last reviewed: April 2019
LEUKINE (sargramostim) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by, or in consultation with an oncologist or hematologist

2. Prescriber must provide clinical documentation that states medication will be used in one of the following conditions:
   a. For use in older adult patients (55 years and older) following induction chemotherapy who have a diagnosis of Acute Myelogenous Leukemia (AML) to shorten time to neutrophil recovery.
   b. For use in patients who have received an allogeneic or autologous bone marrow transplant to accelerate myeloid recovery.
   c. For use in patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed.
   d. For mobilization of peripheral blood progenitor cells or following transplantation of autologous peripheral blood progenitor cells.

Approval will be granted for duration requested not to exceed 3 months.

References
Criteria last reviewed and updated: 03/2017


<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Brand Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine 5% Ointment</td>
<td>XYLOCAINE</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE/NONCOVERAGE

Lidocaine 5% ointment will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The member has a documented trial and failure with Lidocaine 4% cream.
2. The product is being used as a local anesthetic to treat pain, burns or neuropathy.
3. The requested quantity does not exceed 50gm every 30 days or there is documentation to support the necessity of more than 50 grams per 30 days.

Approval Duration: 12 months

References:

Criteria last reviewed and updated: 03/2019
Linzess is a guanylate cyclase-C agonist indicated in adults for the treatment chronic idiopathic constipation and irritable bowel syndrome with constipation (IBS-C).

Linzess will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has one of the following diagnoses, occurring for at least 6 months:
   a. For the treatment of chronic idiopathic constipation in adults, when prescribed by or in consultation with a specialist in gastroenterology, and other possible causative conditions have been appropriately treated first.
   b. For the treatment of IBS-C in members 18 years and older, when prescribed by, or in consultation with a specialist in gastroenterology, and IBS has first been appropriately treated.

2. Recent trial and failure of both of the following. Documentation must include dates of trial and failure in the chart notes and supported within last 90 days of prescription claims history. Trial must consist of a minimum of 30 days.
   a. An increase in dietary fiber by food and by fiber supplements (Metamucil).
   b. Polyethylene glycol (Miralax).

Approval length: 6 months initially then 12 months thereafter.

Continuation criteria:

1. Consistent prescription claim history. If non-adherence is observed, a re-trial of first line therapy will be required.
2. Documentation member is receiving a positive clinical response defined as increase in SBMs per week.

References:

Criteria reviewed/revised: 05/2019
The long-acting narcotic analgesics listed above will be considered for coverage under the pharmacy benefit program when the following criteria are met:

A. The member is 18 years or older with moderate to severe chronic pain requiring a continuous, around-the-clock analgesic. Chronic pain defined as pain lasting longer than 3 months outside of active cancer treatment, palliative care, and end-of-life care.

**Note:** If an active oncology diagnosis exists and the prescriber is an oncologist the PA may be overridden at the pharmacy or health plan level with ICD-10 of G89.3 (neoplasm related pain) for approval.

B. All of the following is required as documentation by notes or by labs where applicable with the prior authorization request:

1. Comprehensive pain related medical exam including chronic pain treatment plan.

2. The member has an adequate trial and failure (at least 30 days) of non-pharmacologic therapy (e.g. physical therapy, chiropracy, surgery, etc.) AND non-opioid medications (e.g. NSAIDS, anticonvulsants, topical anesthetics, muscle relaxants, etc.) before opioids were prescribed.

3. A pain management specialist or other specialist (e.g. neurologist, orthopedist, etc.) has assessed the pain related diagnosis. If documented that a specialist is unavailable then requests may be submitted by a primary care provider (PCP).

4. The member has been educated by the prescriber on the potential side effects and risks of using opioid analgesics.

5. The member has been screened for behaviors indicative of a developing substance abuse disorder including but not limited to abuse/misuse of current prescriptions by **ALL** of the following:
   a. Notation that the prescriber has reviewed the member’s profile in the AZ CSPMP within the last 30 days from the date of the request.  

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### LONG-ACTING OPIOIDS

<table>
<thead>
<tr>
<th>PREFERRED PRODUCTS:</th>
<th>NON-PREFERRED PRODUCTS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butrans patches (brand name)</td>
<td>Belbuca, Exalgo, Fentanyl (37.5mcg, 62.5mcg, 87.5mcg)</td>
</tr>
<tr>
<td>Embeda capsules</td>
<td>Hydromorphone ER, Hysingla, Kadian ER, Methadone,</td>
</tr>
<tr>
<td>Fentanyl patches (certain strengths)</td>
<td>Morphone Sulfate ER capsules, Nucynta ER, Oxycontin,</td>
</tr>
<tr>
<td>Morphine Sulfate ER tablets</td>
<td>Oxycodone ER tabs, Oxymorphone ER, Zohydro ER</td>
</tr>
<tr>
<td>Tramadol ER tablets</td>
<td></td>
</tr>
<tr>
<td>Xtampza ER capsules</td>
<td></td>
</tr>
</tbody>
</table>
**Note:** Oncologists prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to review the member’s CSPMP profile.  
b. Submission of urinary drug screen results dated within the past 4 months.¹,³

**Note:** Oncologists who are prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to conduct a UDS.

c. Notation supporting that the member does not display behaviors of developing an opioid use disorder.³,⁷

5. Coordination of care must be occurring by the prescriber if any of the following are applicable:
   a. The prescriber is not the PCP.¹
   b. The patient is being treated by a behavioral health provider and the prescriber is not the BH provider.¹
   c. The patient is in a substance abuse treatment program and there is a patient signed medical release to share information between providers.

6. The member must be considered opioid-tolerant prior to approval for the following **requested** opioids and their respective strengths listed below. If the request is for any of the following strengths listed below then criteria #7 applies.
   - Butrans ≥ 7.5 mcg/hour
   - Embeda ≥ 100mg/4mg
   - Any strength of Fentanyl patches
   - Morphine daily dose ≥ 60mg
   - Any strength of hydromorphone ER
   - Oxycodone ER/Oxycontin daily dose ≥ 80mg
   - Xtampza ER daily dose ≥ 72mg

7. If applicable, opioid tolerant defined as members who have been taking the following for one week or longer.
   a. Morphine 60 mg/day or more.
   b. Fentanyl transdermal 25 mcg/hr or more.
   c. Oral oxycodone 30 mg/day or more.
   d. Oral hydromorphone 8 mg/day or more.
   e. Oral oxymorphone 25 mg/day or more.
   f. An equianalgesic dose of another opioid.

8. Submission of a signed patient/provider agreement form for pain treatment with opioid medications.

9. **For NON-PREFERRED Long-Acting Opioids:**
   a. Documentation of trial and failure of at least THREE formulary products.
C. **Quantity Limits (QL):**
   - Butrans patches - #4/28 days
   - Embeda capsules - #30/30 days
   - Fentanyl patches - #15/30 days
   - Morphine sulfate ER tablets - #90/30 days
   - Xtampza ER - #60/30 days
   - Tramadol ER #30/30 days
   
   a. Requests for exceeding quantity limits must include the following:
      i. The maximal doses specified under the quantity restriction has been tried for an adequate period of time and deemed ineffective.
      ii. Clinical rationale for the requested dosage, quantity, or duration has been provided.
      iii. The requested dosage, quantity, or duration is known to be safe and effective based on clinical evidence contained in peer-reviewed literature, accepted standards of medical practice, or compendia.

   **Note:** For patients under the age of 18, prescriptions for all opioid medications (long and short acting) will be limited to a 5 day supply except in the case of cancer, other chronic disease, or traumatic injury which will be reviewed on a case-by-case basis.

   1. For diagnosis of cancer or other chronic disease, approval duration will be for six months.
   2. For traumatic injury, approval duration will be for the requested duration or up to a maximum of three months.

   **Approval Length:** 6 months.

   **Continuation Criteria:**
   1. Notation that the member is adhering to the chronic pain treatment plan including adherence to a tapering protocol if applicable and use of non-opioid medications included in the treatment plan.
   2. The prescriber has reviewed the member’s profile in the AZ CSPMP within the last 30 days from the date of the renewal request.
   3. A random drug screen collected within the past 4 months has been submitted and is appropriate.
   4. Notation that the member does not display behaviors of developing an opioid use disorder.
   5. Coordination of care is occurring between the appropriate providers as described in this policy.
   6. If there have been any violations of the patient/provider agreement, notes address the violation(s).

   **References:**

Criteria updated 7/2019
Lupron-Depot (leuprolide) is a gonadotropin releasing hormone (GnRH) agonist. Leuprolide acts as a potent inhibitor of gonadotropin secretion when given continuously and in therapeutic doses. Human studies indicate that following an initial stimulation of gonadotropins, chronic stimulation with leuprolide acetate results in suppression or "downregulation" of these hormones and consequent suppression of ovarian and testicular steroidogenesis. These effects are reversible on discontinuation of drug therapy. Leuprolide acetate is not active when given orally.

Lupron Depot should be administered under the supervision of a physician for the following indications:

- For the management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot taken with daily norethindrone acetate 5 mg is also indicated for initial management of endometriosis and for the management of recurrence of symptoms. The recommended initial treatment is no more than 6 months. Repeat treatment for endometriosis should be limited to 6 months.
- For the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids) and taken concomitantly with iron therapy. A one-month trial period of iron alone may be attempted before use with Lupron as some patients’ anemia will improve with iron alone. Recommended duration of use is not for more than three months in patients with fibroids.
- For the short-term (6 months) treatment of uterine leiomyoma (fibroids).
- For the palliative treatment of advanced prostate cancer.
- For the treatment of children with central precocious puberty (CPP).

Lupron Depot is available in the following dosage forms:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPRON DEPOT</td>
<td>Leuprolide acetate</td>
</tr>
<tr>
<td>LUPRON DEPOT-PED</td>
<td>Leuprolide acetate</td>
</tr>
<tr>
<td>ELIGARD</td>
<td>Leuprolide acetate</td>
</tr>
</tbody>
</table>

Eligard is also a gonadotropin releasing hormone (GnRH agonist). Eligard is indicated for the palliative treatment of advanced prostate cancer and is available in the following dosage forms:
Lupron or Eligard will be considered for coverage under the pharmacy benefit program when all of the following criteria are met specific to the requested diagnosis and supported by documentation:

**Endometriosis**

1. Prescribed by, or in consultation with a gynecologist.
2. Member is 18 years of age or older.
3. Documented diagnosis of endometriosis confirmed by laparoscopy or laparotomy or if surgical diagnosis is contraindicated, by transvaginal ultrasonography.
4. Documented trial of at least 90 days and failure, defined as no relief of symptoms, of both of the following in the past 12 months:
   a. One oral NSAID medication unless documented contraindication.
   b. One continuous hormonal contraceptive unless documented contraindication or norethindrone for members who cannot use estrogen therapy.

   *Formulary continuous hormonal contraceptives: Medroxyprogesterone acetate IM injection, Ashlyna, Amethia, Amethia Lo, Camrese, Camrese Lo, Daysee, Introvale, Jolessa, Setlakin, and Quasense.*

5. Documented trial and failure of, or contraindication to, levonorgestrel IUD (Mirena, Kyleena). Failure is defined as no improvement in symptoms.
6. Member has not used Lupron for the treatment of endometriosis previously for a treatment course greater than 6 months in total duration.  
   *Note: The initial treatment course is to consist of 6 months taken consecutively. If the request is for treatment after an initial 6 month course has occurred then retreatment criteria in this policy will apply.*
7. Request is for only one of the Lupron strengths listed below.

   *Note: Each Lupron product listed below cannot be combined for additive strength.*

   - Lupron Depot 3.75 mg, for 1-month administration
   - Lupron Depot 11.25 mg, for 3-month administration

**Anemia caused by uterine leiomyoma (fibroids)**

1. Prescribed by, or in consultation with a gynecologist.
2. Member is 18 years of age or older.
3. Documentation submitted to support the intent of use is to improve anemia and/or reduce uterine size for three to six months prior to a planned surgical intervention.
4. Documentation submitted to support a. and b. listed below in entirety.
   a. Anemia caused by uterine leiomyomata (fibroids).
      i. Lab report submitted of a hemoglobin level drawn within last 30 days that supports a hemoglobin level at or below reference lab values.
      ii. Member displays at least two clinical symptoms of anemia such as fatigue, shortness of breath, dizziness, headache, coldness in hands and feet, pale skin, and chest pain.
      iii. Per the treatment plan Lupron will be used concomitantly with iron therapy either by oral or intravenous routes.
   b. Uterine fibroids documented by a current ultrasound.
      i. Surgery is scheduled two to six months from date of request.
      ii. Negative pregnancy test within last 30 days.
5. Request is for only one of the Lupron strengths listed below.
   
   Note: Each Lupron product listed below cannot be combined for additive strength.

- Lupron Depot 3.75 mg, for 1-month administration
- Lupron Depot 11.25 mg, for 3-month administration

**Uterine Leiomyoma**

1. Prescribed by, or in consultation with a gynecologist.
2. Member is 18 years of age or older.
3. Documentation submitted to support reduction in uterine size due to uterine leiomyoma that is symptomatic (e.g. menorrhagia, pelvic pain, pelvic pressure, urinary obstructive symptoms).
4. Uterine fibroids documented by current ultrasound.
5. Documentation submitted to support that surgical intervention is not appropriate and use will be short term (≤ 6 months).

**Central precocious puberty (CPP) for females**

1. Prescribed by, or in consultation with a pediatric endocrinologist.
2. Documentation has been submitted supporting the onset of secondary sexual characteristics earlier than 8 years of age.
3. Member is 12 years of age or younger.
4. A diagnosis of CPP confirmed by submitted lab of an elevated basal luteinizing hormone (LH) level > 0.3 mIU/L.
5. Documentation has been submitted supporting bone age is advanced one year beyond the chronological age.

6. Baseline height and weight are submitted. *Note: Current weight required due to weight based dosing of the drug and height to measure response of drug.*

7. Documentation submitted supporting all of the following have been performed:
   a. Human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor
   b. Adrenal steroid measurements to exclude congenital adrenal hyperplasia
   c. Diagnostic imaging of the brain to rule out intracranial tumor(s)
   d. Pelvic and adrenal ultrasounds to rule out steroid secreting tumors

8. Request is for only one of the Lupron strengths listed below.
   *Note: Each Lupron product listed below cannot be combined for additive strength*
   - Lupron Depot-Ped 7.5 mg, for 1-month administration
   - Lupron Depot-Ped 11.25 mg, for 1-month administration
   - Lupron Depot-Ped 15 mg, for 1-month administration
   - Lupron Depot-Ped 11.25 mg, for 3-month administration
   - Lupron Depot-Ped 30 mg, for 3-month administration

**Central precocious puberty (CPP) for males**

1. Prescribed by, or in consultation with a pediatric endocrinologist.
2. Documentation has been submitted supporting the onset of secondary sexual characteristics earlier than 9 years of age.

3. Member is **13 years of age or younger**.

4. A diagnosis of CPP confirmed by submitted lab of an elevated basal luteinizing hormone (LH) level > 0.3 mIU/L.

5. Documentation has been submitted supporting bone age is advanced one year beyond the chronological age.

6. Baseline height, weight, and LH levels submitted. Current weight is required due to weight based dosing and is consistent with the requested strength.

7. Documentation submitted supporting all of the following have been performed:
   a. Human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor.
   b. Adrenal steroid measurements to exclude congenital adrenal hyperplasia.
   c. Diagnostic imaging of the brain to rule out intracranial tumor(s).
d. Testicular and adrenal ultrasounds to rule out steroid secreting tumors.

8. Request is for only one of the Lupron strengths listed below.  

   Note: Each Lupron product listed below cannot be combined for additive strength.

   - Lupron Depot-Ped 7.5 mg, for 1-month administration
   - Lupron Depot-Ped 11.25 mg, for 1-month administration
   - Lupron Depot-Ped 15 mg, for 1-month administration
   - Lupron Depot-Ped 11.25 mg for 3-month administration
   - Lupron Depot-Ped 30 mg for 3-month administration

Palliative treatment of advanced prostate cancer

1. Prescribed by, or in consultation with an oncologist or urologist.
2. Member is 18 years of age or older.
3. Member has a diagnosis of advanced prostate cancer.  
   Note: Advanced prostate cancer is defined as cancer that has spread outside of the prostate gland, such as but not limited to, into adjacent tissues, lymph nodes, or bone.
4. Request is for only one of the Lupron or Eligard strengths listed below.  
   Note: Each product listed below cannot be combined for additive strength.

   - Lupron 7.5 mg, for 1-month administration
   - Lupron 22.5 mg, for 3-month administration
   - Lupron 30 mg, for 4-month administration
   - Lupron 45 mg, for 6-month administration
   - Eligard 7.5 mg, for 1-month administration
   - Eligard 22.5 mg, for 3-month administration
   - Eligard 30 mg, for 4-month administration
   - Eligard 45 mg, for 6-month administration

Gender Dysphoria disorder in adolescents

1. Documentation submitted from a pediatric endocrinologist or other clinician experienced in pubertal assessment that supports all of the following:
   b. Has confirmed puberty has started in the adolescent (Tanner stage ≥ G2/B2).
   c. Has confirmed that there are no medical contraindications to GnRH agonist treatment.

Other diagnoses

1. Requested off-label diagnosis and dosing are supported for use by one of the following compendia:
   i. American Hospital Formulary Service (AHFS) Compendium.
   ii. Micromedx/DrugDex Compendium with a Class I, Iia, or Iib rating.
iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a *strong recommendation*.


v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) *Category of 1, 2A, or 2B*.

2. If the above listed compendia do not support the use of the requested diagnosis then two published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug and dosing consistent with the diagnosis can be submitted for review.

The clinical trials must be consistent with the drug requested including the dosing and the conclusion by the trial authors must include it is considered safe and effective for the requested use.

**Approval Length:**

1. *Endometriosis* – *Six months* for first treatment course. Six months for the retreatment course. Treatment duration for longer than twelve months is not clinically supported by evidence at this time and is considered experimental.

2. *Anemia caused by uterine leiomyoma (fibroids)* – *Three months* initially, reapproval may occur for another three months based on clinical necessity only if anemia status and/or surgical status is submitted.

3. *Uterine leiomyoma (fibroid)* – Six months initially, reapproval may occur for another 6 months based on clinical necessity.

4. *Central Precocious Puberty for females and males* – *Three months* initially, reapproval may occur up to twelve months if continuation criteria has been met.

5. *Palliative treatment of advanced prostate cancer* – *Three months* initially to evaluate response then up to 12 months thereafter based on clinical response.

6. *Gender dysphoria disorder in adolescents* – *Twelve months*.

**Continuation Criteria:**

1. *Endometriosis*
   
   a. Documentation has been submitted supporting continued treatment or retreatment for six months.
   
   b. Norethindrone acetate 5 mg oral tablets will be taken concurrently with Lupron Depot for the retreatment course and is submitted as a documented part of the treatment plan.

2. *Anemia caused by uterine leiomyoma (fibroids)*
a. Documentation has been submitted supporting continued treatment due to upcoming confirmed surgery date and continued anemia per labs.

3. Uterine leiomyoma (fibroids)
   a. Documentation has been submitted to support continued use and add back therapy with oral medroxyprogesterone or norethindrone will be used in combination for use beyond 6 months.

4. Precocious puberty in females
   a. All of the following must be submitted with documentation: Decreased growth velocity, menses cessation, and arrested pubertal progression (signs of puberty have stabilized).
   b. Current weight is submitted and it is consistent with the dose requested as per the Lupron prescribing information.

5. Precocious puberty in males
   a. Both of the following must be submitted with documentation: Decreased growth velocity and arrested pubertal progression (signs of puberty have stabilized).
   b. Current weight is submitted and it is consistent with the dose requested as per the Lupron prescribing information.

6. Palliative treatment of advanced prostate cancer and other oncology related diagnoses
   a. Documentation the member is responding to treatment and no intolerable side effects are occurring.

7. Gender Dysphoria disorder in adolescents
   a. Documentation has been submitted supporting continued treatment is necessary.

Exclusions:

1. For the diagnosis of precocious puberty, the use of the Lupron Depot 3-month formulation is excluded if this formulation will be active systemically past the full age of 12 for females and age 13 for males. Use of the one-month formulation may be an option instead if this situation applies and if all criteria is met.

2. Use of Lupron or Lupron-Ped for peripheral precocity or benign/non-progressive pubertal variants.

References:


Criteria last updated 6/2019
BRAND LYRICA (pregabalin) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

A. The member must have first tried, failed, or have a documented contraindication to a compliant 60 day trial of the generic product (Pregabalin).

B. The member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Partial-onset seizures: as adjunctive therapy of partial-onset seizures in patients 18 years of age and older.
   a. Member has tried and failed at least 2 generically available anticonvulsants

2. Fibromyalgia
   a. Member has tried and failed duloxetine (generic Cymbalta) at maximum tolerated dose or dose up to 60mg/day for at least 90 days

3. Neuropathic pain associated with diabetic peripheral neuropathy
   a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.

4. Neuropathic pain associated with spinal cord injury
   a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.

5. Postherpetic neuralgia
   a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.

Quantity Level Limits:
1. For the following strengths: 25mg/50mg75mg/100mg/150mg/200mg, QL is #90 every 30 days
2. For the following strengths: 225mg/300mg, QL is #60 every 30 days

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References

Criteria last reviewed and updated: 6/2019
MAKENA will be considered for coverage under the pharmacy benefit program when indicated use is to reduce the risk of preterm birth AND the following criteria are met:

1. Patient is currently pregnant with singleton gestation and is 16 years of age or older
2. Patient has a history of a spontaneous preterm singleton delivery (i.e. delivery of an infant < 37 weeks gestation)
3. Prescribed by, or in consultation with, a provider of obstetrical care
4. Member will begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation

Exclusions:

1. Current or history of thrombosis or thromboembolic disorders
2. History of or known or suspected breast cancer or other hormone-sensitive cancer
3. Undiagnosed abnormal vaginal bleeding unrelated to pregnancy
4. Cholestatic jaundice of pregnancy
5. Liver tumors, benign or malignant, or active liver disease
6. Uncontrolled hypertension
7. Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth

Duration of therapy:

- Continue administration of 250mg intramuscularly once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first

References
Criteria updated: 3/2019
CRITERIA FOR COVERAGE/NONCOVERAGE

The Morphine Equivalent Dose (MED) value is used to evaluate the amount of an opioid a member is using by standardizing opioid doses of different chemical compounds to a level of morphine equivalent. MED is calculated using all of the member’s current opioid prescriptions. Exceptions to the MED dosing limits will be granted when the following criteria are met:

LEVEL OF CARE CHANGE

1. Provider confirms replacement prescription(s) of opioid medication(s) are needed because the patient is physically changing locations and cannot take their prescription with them [such as admission to a long term care (LTC) facility]

   **Authorization Duration:**

   When the above criteria are met, authorization for use will be granted for one time.

PAIN DUE TO CANCER

1. Confirmation that opioids are being used for the management of cancer pain

   **Authorization Duration:**

   When the above criteria are met, authorization for use will be granted for 6 months to override MED Edit.

HOSPICE ENROLLMENT

1. Patient is currently enrolled in hospice

   **Authorization Duration:**

   When the above criteria are met, authorization for use will be granted for 6 months to override MED Edit.
OTHER PAIN

1. A written or verbal supporting statement is received from the requesting prescriber attesting that in his/her clinical judgment, the requested dose exceeding the current cumulative morphine equivalent dose (MED) threshold* is medically required.

*MED is calculated using all of the member’s current opioid prescriptions. *Note: Ask provider, “Will there be a dose escalation in the patient’s opioid utilization in the next 90 days?” If yes, approve MED level 90 daily MED above the rejected level.

Authorization Duration:

When the above criteria are met, authorization for use will be granted for 6 months.

CLINICAL NOTES

A. All opioid medication edits are subject to review and modification (either to increase or decrease existing MED Limits) based on an Exception request received from the member or the member’s provider. The decision to remove, modify, or retain an existing restriction on opioid pain medications will be based on evidence of new clinical information which is documented in the form of a written supporting statement received from the prescriber and which contains all of the required elements as outlined in the criteria above.

REFERENCES


Last revised 6/2019
**Covered products** | **Brand or generic Name**
---|---
Memantine tablets | NAMENDA
Memantine solution | NAMENDA

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Memantine** is an N-methyl-D-aspartate (NMDA) receptor antagonist indicated for the treatment of moderate to severe dementia of the Alzheimer’s type.

The initial recommended dose is 5 mg once daily. Increase the dose in 5 mg increments to a maintenance dose of 10 mg twice daily. A minimum of 1 week of treatment with the previous dose should be observed before increasing the dose.

**Memantine tablets and oral solution** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member must be 18 years old or older.

2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.

3. Documented diagnosis of mild, moderate, or severe dementia associated with Alzheimer’s disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
   a. Between 21 – 24 points for mild disease.
   b. Between 13 – 20 points for moderate disease.
   b. Less than 12 points for severe disease.

OR

Documented diagnosis of multi-infarct (vascular) dementia and brain imaging confirms evidence of cerebrovascular disease (CVD). Cognitive screening test results such as MMSE, mini-cog, 7 minute screen, Montreal Cognitive Assessment (MOCA) or SLUMS must be included.

**Use of memantine in combination with donepezil** will be considered for coverage when the following criteria are met:

1. Notation of moderate to severe disease
2. Notation that member failed to respond to, or had inadequate response to compliant use of monotherapy for at least 60 days.

**Quantity Limits:**

Memantine tablets – Up to #60 per 30 days

Memantine solution – Up to 600 mL per 30 days

**Length of Approval:** Six months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

**Continuation Criteria:**

1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score for dementia related to Alzheimer’s Disease.
2. Documentation member is receiving a positive clinical response evidenced by an improvement in cognitive testing for vascular dementia.

**Exclusions:**

1. Not for use for other non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.

**References:**

**Covered Product** | **Brand Reference**
---|---
modafinil | PROVIGIL

**CRITERIA FOR COVERAGE/NONCOVERAGE**

*Provigil (modafinil)* will be considered for coverage under the pharmacy benefit program for all patients when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Diagnosis of *Narcolepsy* as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

2. Diagnosis of *Obstructive sleep apnea* as defined by (a) or (b) below AND member must meet criteria (c) below:
   a. 15 or more obstructive respiratory events (apneas, hypopneas, or respiratory effort related arousals [RERA]) per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)
   b. 5 or more obstructive respiratory events (apneas, hypopneas, or respiratory effort related arousals [RERA]) per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) AND the member has one of the following symptoms
      - Unintentional sleep episodes during wakefulness
      - Daytime sleepiness
      - Unrefreshing sleep
      - Fatigue
      - Insomnia
      - Waking up breath holding, gasping, or choking
      - Loud snoring
      - Breathing interruptions during sleep
   c. Member has been fully compliant with the standard treatments for the underlying obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BPAP], etc.) that have been used for 3 months or longer
   d. For reauthorization of continued use, member continues to be fully compliant on concurrent standard treatment(s) for the underlying obstruction (e.g., CPAP, BPAP, etc.) AND member is experiencing relief of symptomatic hypersomnolence with modafinil

3. Diagnosis of *Shift-work sleep disorder* confirmed by (a) or (b) below:
a. Symptoms of excessive sleepiness or insomnia, for at least 3 months, which is temporally associated with a work period (usually night work) that occurs during the habitual sleep phase
b. Sleep study demonstrating loss of a normal sleep wake pattern (i.e., disturbed chronobiologic rhythmicity)

4. To improve wakefulness in adult patients with shift-work sleep disorder.

Authorization for continued use shall be reviewed at least every 12 months to confirm that the patient has not experienced positive response to therapy

References
Criteria last reviewed and updated: 03/2017; Last reviewed April 2019
MULTIPLE SCLEROSIS INJECTABLE MEDICATIONS

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPAXONE 20mg (brand name only)</td>
<td>Glatiramer acetate 20mg</td>
</tr>
<tr>
<td>Glatopa 40mg</td>
<td></td>
</tr>
<tr>
<td>AVONEX</td>
<td>Interferon beta-1a</td>
</tr>
<tr>
<td>BETASERON</td>
<td>Interferon beta-1b</td>
</tr>
<tr>
<td>REBIF Rebidose</td>
<td>Interferon beta-1a</td>
</tr>
<tr>
<td>PLEGRIDY</td>
<td>Peginterferon beta-1a</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE/NON-COVERAGE

Copaxone is indicated for the treatment of patients with relapsing forms of multiple sclerosis. The active ingredient is glatiramer and the mechanism by which its effect is exerted is unknown but thought to be due to modification of immune processes.

Avonex, Rebif, Betaseron, and Plegridy are interferon beta products indicated for the treatment of patients with relapsing forms of multiple sclerosis.

The above medications will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by, or in consultation with a neurologist or multiple sclerosis specialist.
2. Must be 18 years of age or older.

Note: There are four types of multiple sclerosis. Secondary-Progressive is considered a relapsing form if a patient is having relapses. Primary-Progressive is not a relapsing form of multiple sclerosis.

- **Relapsing-Remitting MS (RRMS).** This is the most common form of multiple sclerosis. About 85% of people with MS are initially diagnosed with RRMS. People with RRMS have temporary periods called relapses, flare-ups or exacerbations, when new symptoms appear.

- **Secondary-Progressive MS (SPMS).** In SPMS, symptoms worsen more steadily over time, with or without the occurrence of relapses and remissions. Most people who are diagnosed with RRMS will transition to SPMS at some point.

- **Primary-Progressive MS (PPMS).** This type of MS is not very common, occurring in about 10% of people with MS. PPMS is characterized by...
slowly worsening symptoms from the beginning, with no relapses or remissions

- **Progressive-Relapsing MS (PRMS).** A rare form of MS (5%), PRMS is characterized by a steadily worsening disease state from the beginning, with acute relapses but no remissions, with or without recovery

4. For Avonex, Rebif, Betaseron, and Plegridy, Baseline liver function tests are drawn and there is no serious hepatotoxicity

**Appropriate, approvable dosing for each product is as follows:**

- **Copaxone/Glatopa:** Request is for either Copaxone (brand name) 20 mg/mL daily or Glatopa 40 mg/mL three times a week.
- **Avonex:** Request is for Avonex to be injected once a week.
- **Betaseron:** Request is for Betaseron to be injected every other day.
- **Rebif:** Request is for Rebif to be injected three times a week.
- **Plegridy:** Request is for Plegridy to be injected every 14 days.

**Exclusions:**

1. If the member has a non-relapsing form of multiple sclerosis such as primary progressive MS. The efficacy of these products in this policy has not been established in patients with MS with non-relapsing forms of MS.

2. Concurrent use with other multiple sclerosis disease-modifying agents.

   *Note: An exception is the use of Ampyra (dalfampridine).*

**Approval length:** 12 months

**Continuation criteria:**

1. Member has been re-evaluated in the last twelve months and documentation submitted supports disease stabilization or improvement.

**References:**

8. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, CO, USA.

Criteria reviewed/revised 6/2019
MULTIPLE SCLEROSIS ORAL MEDICATIONS

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>GILENYA</td>
<td>Fingolimod</td>
</tr>
<tr>
<td>TECFIDERA</td>
<td>Dimethyl fumarate</td>
</tr>
<tr>
<td>AUBAGIO</td>
<td>Teriflunomide</td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE/NON-COVERAGE

Gilenya is a sphingosine 1-phosphaste receptor modulator in an oral capsule indicated for the treatment of relapsing forms of multiple sclerosis (MS).

Tecfidera is a delayed-release oral capsule indicated for the treatment of relapsing forms of MS. The mechanism by which dimethyl fumarate exerts its therapeutic effect is unknown.

Aubagio is an oral tablet pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of MS.

The above medications will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by, or in consultation with a neurologist or multiple sclerosis specialist.
2. Must be 18 years of age or older, except for Gilenya.
   
   Note: There are four types of multiple sclerosis. Secondary-Progressive is considered a relapsing form if a patient is having relapses. Primary-Progressive is not a relapsing form of multiple sclerosis.
   
   - **Relapsing-Remitting MS (RRMS).** This is the most common form of multiple sclerosis. About 85% of people with MS are initially diagnosed with RRMS. People with RRMS have temporary periods called relapses, flare-ups or exacerbations, when new symptoms appear
   
   - **Secondary-Progressive MS (SPMS).** In SPMS, symptoms worsen more steadily over time, with or without the occurrence of relapses and remissions. Most people who are diagnosed with RRMS will transition to SPMS at some point
   
   - **Primary-Progressive MS (PPMS).** This type of MS is not very common, occurring in about 10% of people with MS. PPMS is characterized by slowly worsening symptoms from the beginning, with no relapses or remissions
   
   - **Progressive-Relapsing MS (PRMS).** A rare form of MS (5%), PRMS is characterized by a steadily worsening disease state from the beginning, with acute relapses but no remissions, with or without recovery

4. Baseline liver function tests have been drawn; member does not have serious hepatotoxicity.

AND each of the below criteria is met for the respective requested medication:
**Gilenya**

1. Request is for one capsule to be taken once daily.
2. Member is age 10 years or older.
3. In the previous 6 months, member has not experienced a myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure (requiring hospitalization or Class III/IV heart failure), treatment with a Class 1a or Class III anti-arrhythmic drug, or has a baseline QTc interval $\geq 500$ ms.

**Tecfidera**

1. Request is for Tecfidera to be taken twice a day.

**Aubagio**

1. Request is for one tablet to be taken once a day.
2. Documentation submitted and/or prescription claim history supports all of the following is not occurring:
   - Member is a pregnant woman or woman of childbearing potential not using reliable contraception
   - Co-administration with leflunomide
   - Co-administration with rosuvastatin doses greater than 10mg

**Exclusions:**

1. If the member has a non-relapsing form of multiple sclerosis such as primary progressive MS. The efficacy of these products in this policy has not been established in patients with MS with non-relapsing forms of MS.
2. Concurrent use with other multiple sclerosis disease-modifying agents.
   
   *Note: An exception is the concurrent use of Ampyra (dalfampridine).*

**Approval length:** 12 months

**Continuation criteria:**

1. Member has been re-evaluated in the last twelve months and documentation submitted supports disease stabilization or improvement.
References:
6. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, CO, USA.
### Brand Name | Generic Name
---|---
MYALEPT | metreleptin

### CRITERIA FOR COVERAGE/NONCOVERAGE

**MYALEPT™ (metreleptin)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a diagnosis of congenital (CGL) or acquired generalized lipodystrophy (AGL) with leptin deficiency
2. Member has one or more of the following:
   a. Hypertriglyceridemia (greater than 500 mg/dl) and/or increased fasting glucose (greater than 126mg/dl)
   b. Diabetes mellitus (DM)
3. Baseline A1c, triglycerides and fasting glucose have been drawn prior to starting Myalept and submitted with prior authorization request
4. Member had trial and failure with standard therapy for lipid and diabetic management (e.g., metformin, pioglitazone, high dose insulin, statins and/or fibrates, diet/exercise).
5. Prescribed by or in consultation with an endocrinologist or cardiologist

**Initial Authorization: 12 months**

**Reauthorization criteria:**

Member has had improvement in least one of following from baseline: A1c, triglycerides and/or fasting glucose levels.

**Renewal authorization: 12 months**

**Exclusion criteria:**

- Treatment of HIV-related lipodystrophy
- Treatment of metabolic disease, including diabetes mellitus and hypertriglyceridemia, in patients who do not have congenital or acquired generalized lipodystrophy
- Treatment of liver disease including nonalcoholic steatohepatitis (NASH) Treatment of complications of partial lipodystrophy

**References**


Criteria last reviewed and updated: 05/2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>MYTESI (formerly Fulyzaq)</td>
<td>crofelemer</td>
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**CRITERIA FOR COVERAGE/NONCOVERAGE**

MYTESI/crofelemer will be considered for coverage under the pharmacy benefit program when the following criteria are met:

a) Member is 18 years of age or older with HIV/AIDS and is taking antiretroviral therapy and is using Mytesi for symptomatic relief of non-infectious diarrhea.

b) Infectious diarrhea has been ruled out (e.g. diarrhea due to cryptosporidiosis, clostridium difficile, etc.).

c) Member has documented trial/failure, intolerance or contraindication to at least one anti-diarrheal medication such as loperamide or diphenoxylate/atropine.

MYTESI™ (crofelemer) will be subject to the following quantity limit: 2 tablets/day.

Initial authorizations will be granted for 3 months. Reauthorizations for continued use shall be reviewed yearly. Renewal criteria shall confirm the member has had an objective response to therapy, defined as improvement in diarrhea symptoms.

References


Criteria last reviewed: 5/2019
**Brand Name** | **Generic Name**
---|---
NEUPOGEN | filgrastim

**CRITERIA FOR COVERAGE/NONCOVERAGE**

*Neupogen* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by, or in consultation with, an oncologist or hematologist
2. Neupogen is being used for one of the following:
   A. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy.
   B. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation.
   C. Prophylaxis of febrile neutropenia in patients with acute myeloid leukemia receiving chemotherapy.
   D. Harvesting of peripheral blood stem cells -- for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
   E. Chronic severe, symptomatic neutropenic disorder (e.g. congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia)
   F. Radiation injury of bone marrow due to acute exposure of myelosuppressive radiation doses.

**Approval duration:** 6 months

**References**

Criteria last reviewed and updated 5/2019
NEVANAC® (Nepafenac) 0.1% will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Patient is having cataract surgery and Nevanac will be used for the treatment of post-operative pain and inflammation.

2. Member is 10 years of age or older.

Approval length: One month

Quantity limits: 1 bottle (3ml) per surgical eye

References:

Criteria updated 4/2019
CRITERIA FOR COVERAGE/NONCOVERAGE

In accordance with AHCCCS regulations, Antipsychotics are covered under the Plan benefit only when prescribed by a provider who specializes in Behavioral Health (BH).

When a request is submitted to the plan for coverage of an antipsychotic prescribed by a non-BH provider, temporary overrides may be granted when the following are met:

1. The medication has been prescribed for the treatment of a FDA-approved indication, or clinically accepted indication supported by medical literature and is medically necessary.
2. Medication is on formulary.
3. The patient has had an inadequate response or intolerance to other medications appropriate for the submitted diagnosis.
4. The patient is being transitioned to a behavioral health provider.

Criteria created: 6/2019
Criteria Name

Non Formulary, Quantity Limit Exception, and Brand Name DAW requests

CRITERIA FOR COVERAGE/NON-COVERAGE

Requests for non-formulary drugs or for drugs exceeding stated quantity limits will be considered for coverage under the pharmacy benefit program when all of following criteria are met:

1. Drug (and prescription) must be prescribed by a Health Choice contracted provider.

2. Documented trial and failure of ALL available formulary and preferred alternatives in a specific drug class unless contraindication exists or previous established intolerance that is documented by the prescriber. Documentation must include dates of trial and failure in the chart notes and supported by prescription claims history.

3. If all formulary and preferred alternatives in a specific drug class have been tried and failed or established documented intolerance or contraindication exists then the requested medication and the diagnosis must meet either a, b, or c listed below.

   a. Requested medication and the diagnosis must meet the FDA indication in full.

      In full defined as indication, drug strength, directions, dosing modifications, warnings, contraindications, any black box warnings, and any other pertinent clinical information as per the prescribing information. Documentation is required and all of the below must be met:

         i. Recent chart notes that include the treatment plan with the requested non-formulary medication or quantity limit.

         ii. Lab work pertaining to drug as indicated per the FDA prescribing information.

        Example: Hepatic, renal function, or other labs that would affect the approvable quantity if impairment exists.
b. **Compendia.** If the FDA indication is not met in full then the request is considered off-label and must meet one of the following compendia in full.

i. American Hospital Formulary Service (AHFS) Compendium.

ii. Micromedex/DrugDex Compendium with a *Class I, IIa, or IIb rating.*

iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a *strong recommendation.*


v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) *Category of 1, 2A, or 2B.*

c. **Evidence.** If the FDA indication or compendia is not met then two published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug and/or quantity with the diagnosis can be submitted for review.

The clinical trials must be consistent with the drug requested including the dosing. The conclusion by the trial authors must include it is considered safe and effective for the requested use.

**Clinical Trial Phases:**

- **Preclinical research:** A trial done in a lab and not tested in animals or humans.
- **Phase 0:** The first clinical trials to be done among people. In these trials a very small dose of a drug is given to about 10 to 15 people.

- **Phase I:** An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects.

- **Phase II:** An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete.

- **Phase III:** Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are
usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way.

- **Phase IV**: After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment’s risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials.

**Requests for a DAW (dispense as written) brand name drug when a formulary generic equivalent option is available** will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The prescriber has written on the prescription “Dispense as Written” or other equivalent wording.
2. The member has a documented trial and failure of all formulary and non-formulary alternatives within the same drug class as the requested medication per the chart notes submitted and per prescription claim history.
3. The member has a documented trial, of adequate duration, and failure of up to three AB-rated generic equivalents to the brand name drug being requested. These three products must be from different manufacturers.
4. The member has a documented known allergic reaction to an excipient (inactive ingredient) that is present in the generic formulation, but is absent in the brand name equivalent.

**OR**

The member has a documented life-threatening side effect with a generic medication that required medical intervention and that side effect did not occur with previous experience with the brand.

5. The prescriber has completed and submitted an FDA MedWatch Adverse Event Reporting Form regarding the use of the generic product. The prescriber must provide a copy of the completed MedWatch form. Authorization will not be considered unless the form is completed and submitted to the FDA.

Information regarding MedWatch, the FDA Safety Information and Adverse Event Reporting Program can be found at: [www.fda.gov/Safety/MedWatch](http://www.fda.gov/Safety/MedWatch)

The MedWatch form for healthcare professionals can be found at:

[www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf)
Approval length: Up to 12 months if clinically appropriate.

Continuation criteria:
1. Chart notes documenting a positive response to therapy and no intolerable side effects. Labs may be required to support response to therapy if indicated per the prescribing information.

References:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORTHERA</td>
<td>droxidopa</td>
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**CRITERIA FOR COVERAGE/NONCOVERAGE**

NORTHERA™ (droxidopa) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Patient has a diagnosis of neurogenic orthostatic hypotension (NOH)
   
   AND
   
   2. NOH is due to one of the following:
      a. primary autonomic failure (Parkinson’s disease, multiple system atrophy, and pure autonomic failure)
      b. dopamine beta-hydroxylase deficiency (DBH)
      c. non-diabetic autonomic neuropathy (NDAN)
   
   AND
   
   3. Patient has symptoms of NOH:
      a. Orthostatic dizziness
      b. Lightheadedness
      c. “feeling that you are about to black out”
   
   AND
   
   4. Patient is an adult 18 years of age or older
   
   AND
   
   5. Patient has tried and had an inadequate response, contraindication or intolerance to midodrine
   
   6. Patient will be monitored for supine hypertension prior to and during treatment (systolic blood pressure (SBP) >180 mmHg or diastolic blood pressure (DBP) >110 mmHg).

**Authorization:**

Authorization will be for 3 months.

Reauthorization every 3 months requires confirmation the following:

7. Patient had improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint or feeling like patient may black out
   
   8. Patient will be monitored for supine hypertension during treatment (systolic blood pressure (SBP) >180 mmHg or diastolic blood pressure (DBP) >110 mmHg)

**References**


Criteria last reviewed and updated: 05/2019
NOXAFIL (posaconazole) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by or in consult with an Infectious Disease specialist, a transplant specialist or an oncologist
2. Age 13 years and older

AND

The member has one of the following diagnoses:

1. Oropharyngeal Candidiasis: Member had trial and failure of fluconazole OR refractory to fluconazole and/or itraconazole.
2. Prophylaxis of invasive Aspergillosis or Candidiasis infection in member who is at high risk of developing invasive Aspergillosis or Candidiasis due to being severely immunocompromised, such as an allogenic hemotopoietic stem cell transplant (HSCT) recipients; or a patient with a hematologic malignancies (leukemia, lymphoma, myelodysplastic syndrome) with prolonged neutropenia from chemotherapy or a high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant members.
3. Allergic Bronchopulmonary Aspergillosis

Approval duration for initial/continuation therapy:

Oropharyngeal candidiasis: 14 days

Refractory Oropharyngeal candidiasis/Invasive Aspergillus and candida infections: 12 months

Approval criteria for continuation of therapy:

Member is responding positive to therapy and there are no contraindications to therapy.

References

Criteria last updated: 03/2019
Nuedexta is a combination product of dextromethorphan hydrobromide and quinidine sulfate indicated for the treatment of pseudobulbar affect (PBA).

Nuedexta will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Prescribed by, or in consultation with a neurologist.
2. Member is age 18 years of age or older.
3. Documented diagnosis of pseudobulbar affect caused by one of the following neurologic conditions: amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), Parkinson’s disease (PD), Alzheimer’s disease (AD), stroke, or traumatic brain injury (TBI).
4. Member has not had an exacerbation of the underlying neurologic condition in the two months before starting Nuedexta.
5. Documentation of both of the following: (i) member has at least 5 episodes of inappropriate laughing or crying per day (including number of episodes per day). (ii) Center for Neurologic Study-Lability Scale (CNSLS) score of at least 13 points.
6. Member is not currently taking any drugs, verified by prescription claims history, that have a contraindication for use with Nuedexta. If a drug interaction exists then corresponding dose adjustment per the Nuedexta prescribing label has occurred.
7. Must not have a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, heart failure, complete AV (atrioventricular) block without an implanted pacemaker, or be at high risk of complete AV block.

Approval Length: Three months initially then up to twelve months thereafter based on clinical response.
Quantity Limits: Up to 60 capsules per 30 days.
Continuation Criteria:
1. Documentation of one of the following, showing improvement in symptoms: (i) decrease of at least 50% in number of daily episodes of inappropriate laughing or crying, including number of episodes member is now having. (ii) improvement of at least 5 points in CNSLS from baseline.

References:


Criteria last updated 6/2019

**Research/clinical notes:**


What pharmacologic measures reduce pseudobulbar affect? Pseudobulbar affect, excessive laughing or crying, or involuntary emotional expression disorder affects 20%–50% of patients with ALS, especially in pseudobulbar palsy. Although it is not a mood disorder, antidepressants are frequently employed.

A fixed-dose combination of dextromethorphan (DM)/quinidine (Q) (30 mg DM/30 mg Q BID) for treatment of pseudobulbar affect in ALS (Class I) reduced the frequency and severity of laughing and crying behaviors compared to either DM (p 0.001) or Q alone (p 0.001). Side effects were dizziness, nausea, and somnolence, which accounted for termination of treatment in 24% with DM/Q compared to 6% with DM and 5% with Q. DM/Q is not yet approved by the US Food and Drug Administration (FDA). Conclusions. The combination of DM/Q is probably effective for pseudobulbar affect in ALS (1 Class I study), although side effects may limit its usefulness. Recommendation. If approved by the FDA, and if side effects are acceptable, DM/Q should be considered for symptoms of pseudobulbar affect in patients with ALS (Level B).

*UpToDate:*
Pseudobulbar affect — Pseudobulbar affect (also called emotional lability or emotional incontinence) is a term that describes sudden uncontrollable outbursts of laughter or tearfulness that occur in many patients with ALS as the disease progresses. It is a result of bilateral corticobulbar tract degeneration. Although its prevalence is unknown, limited retrospective data suggest that pseudobulbar palsy may affect close to 50 percent of patients with ALS (though not all affected need treatment for it), and it is more common in those with the bulbar form.

Treatment options for pseudobulbar affect include:

- The combination drug dextromethorphan-quinidine (20 mg/10 mg); the recommended starting dose is one capsule once daily for seven days, then increase to one capsule twice daily with periodic reassessment to determine if continued use is necessary.
- Tricyclic antidepressants such as amitriptyline 10 to 150 mg at bedtime; the starting dose is 10 to 25 mg at bedtime, and dosing is increased slowly as needed.
- Selective serotonin reuptake inhibitors such as fluvoxamine 100 to 200 mg daily.

A controlled trial of 140 subjects with ALS found that twice-daily treatment with AVP-923, a combination of dextromethorphan and quinidine (30 mg/30 mg), was effective for reducing the frequency and severity of pathologic laughter and crying compared with either drug alone. Treatment with AVP-923 was also associated with an improvement in quality of life. Adverse events with AVP-923 were described as mostly mild or moderate and included nausea, dizziness, and gastrointestinal complaints. Additional side effects such as muscle cramps, muscle spasms, and weakness appeared to be related to ALS. However, treatment-related discontinuation of AVP-923 during the four-week duration of the trial was 24 percent, compared with 6 percent for dextromethorphan and 8 percent for quinidine. A later trial found that two formulations using low-dose quinidine in the combination drug dextromethorphan-quinidine (30 mg/10 mg or 20 mg/10 mg) were both superior to placebo and were associated with lower discontinuation rates than observed for the higher-dose formulation evaluated in the earlier trial. The formulation of dextromethorphan-quinidine (20 mg/10 mg) approved for marketing in the United States and Canada differs from that of AVP-923 (30 mg/30 mg).

Dextromethorphan is a weak N-methyl-D-aspartate (NMDA) receptor antagonist, and it is proposed to act as an agonist at the sigma 1 receptor. However, its mechanism of action for treating pseudobulbar palsy is unknown. The rationale for using the combination medication is that dextromethorphan is rapidly metabolized in approximately 90 percent of the Caucasian population by the cytochrome P450 2D6 enzyme (CYP2D6), and quinidine is a selective CYP2D6 inhibitor. Thus, the coadministration of quinidine reduces the metabolism and maintains serum plasma levels of dextromethorphan.

Neither amitriptyline nor fluvoxamine have been studied for the treatment of pseudobulbar palsy in controlled trials, and clinical experience suggests that most patients with ALS do not notice significant improvement with these agents. However, the results of several small, placebo-controlled, randomized trials involving patients with stroke suggest that some aspects of pseudobulbar affect respond to treatment with antidepressants, including nortriptyline, sertraline, and fluoxetine.


Question. What are the effective treatments for disorders of affect in individuals with MS? Analysis. One Class II study addressed this question for PBA in a randomized controlled trial comparing
dextromethorphan and quinidine (DM/Q) with placebo. Investigators measured presence and severity of PBA with the CNS-LSe18 and determined the adjusted mean change in CNS-LS score at 4 assessments over 12 weeks. Secondary outcomes included the number of episodes of laughing or crying, or both, between visits and the proportions of subjects with complete symptom remission and at least a 3-point decrease in mean CNS-LS score. Investigators also used a pain rating scale and measured quality of life and relationships with visual analog scales. Treated subjects had significantly greater reductions in mean CNS-LS scores at all 4 assessments, and significantly more treated subjects showed a 3-point or greater mean score decrease (83.6% treated vs 49.3% untreated; p < 0.0001, risk difference 34%, 95% confidence interval 21%–48%). Treated subjects also improved significantly on all secondary outcome measures. Dizziness was the only adverse event that occurred more frequently in the treated (26.3%) vs placebo (9.5%) group, and only one treated subject rated it as severe. This study is Class II because of dropout rates (27.6% treated, 28.4% placebo). Conclusion and recommendations. DM/Q is possibly effective and safe and may be considered for treating individuals with MS with PBA (Level C, 1 Class II study). Clinical context. DM/Q is the only drug approved by the US Food and Drug Administration for PBA treatment, although other drugs are used in clinical practice (e.g., selective serotonin reuptake inhibitors, tricyclic antidepressants). There are no randomized placebo-controlled trials of these other agents.
**CRITERIA FOR COVERAGE/NON-COVERAGE**

**Olumiant** is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Limitation of Use: Use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

**Olumiant** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or provider attestation.
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated:
      i. Methotrexate for ≥ 3 consecutive months
      ii. If documented intolerance or known contraindication to MTX, then one of the following disease-modifying antirheumatic agent for ≥ 3 consecutive months:
         • Hydroxychloroquine
         • Sulfasalazine
         • Leflunomide
   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both **Humira** (adalimumab) and **Enbrel** (etanercept).
   h. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

**Approval Length:** Six months initially then up to 12 months thereafter based on clinical response.
**Quantity Limits:** Up to 30 tablets for 30 days (one tablet daily).

**Continuation Criteria:**
1. Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.

**Exclusions:**
1. Needle phobia is not considered a clinical reason for the use of Olumiant instead of the required alternatives unless it meets DSM-V-TR 300.29 (Specific Phobia).
2. Concomitant use with other biologic DMARD medications (oral and injectable).
3. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
4. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

References:


Criteria updated: 5/2019
### Formulary Oral Oncology Agents – PA required

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**CRITERIA FOR COVERAGE/NON-COVERAGE**

Formulary oral oncology medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by an oncologist or by a mid-level clinician directly supervised by an oncologist.

2. **Requested medication(s) and the diagnosis must meet either a, b, or c.**
   If the request is for a regimen comprised of more than one oncology drug, including injectable or infused drugs, then the entire regimen still needs to be reviewed to meet either a., b., or c. listed below.

   a. **FDA indication.** Documentation must be submitted that the requested drug meets the FDA indication(s) in full. In full is defined as following the specified indication, strength and directions
including dosing cycle if applicable, any genetic testing requirements, and acknowledging any applicable black box warnings.

b. **Compendia.** If the FDA indication is not met in full, then the request is considered off-label and must meet one of the following compendia.

i. American Hospital Formulary Service (AHFS) Compendium.
ii. Micromedex/DrugDex Compendium with a Class I, IIA, or IIB rating.
iii. Elsevier Gold Standard’s Clinical Pharmacology Compendium with a strong recommendation.
v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) Category of 1, 2A, or 2B.

c. **Evidence.** If the FDA indication or compendia is not met then two published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug or drug regimen and the diagnosis can be submitted for review. The clinical trials must be consistent with the drug or drug regimen requested including the dosing and/or dosing cycle. The conclusion by the trial authors must include it is considered safe and effective for the requested use. Clinical Trial Phases:

- Preclinical research: A trial done in a lab and not tested in animals or humans.
- Phase 0: The first clinical trials to be done among people. In these trials a very small dose of a drug is given to about 10 to 15 people.
- Phase I: An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects.
- Phase II: An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete.
- Phase III: Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way.
- Phase IV: After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment’s risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials.

3. **Documentation required (ALL must be met unless indicated):**

a. Chart notes dated within 3 to 6 months supporting the oncology diagnosis and treatment plan. Treatment plan must include the drug or the drug regimen requested and current BSA or weight if applicable to support the approvable quantity.
b. Lab work pertaining to drug or drug regimen requested. All of the below may or may not be applicable.
   i. Genetic test lab report(s) to support a specific mutation. Example: The FDA indication for Tagrisso© requires mutation T790M be present.
   ii. Other lab report(s) to support the diagnosis. Example: The FDA indication for Ibrance© requires the patient to be HER2 negative and hormone receptor (HR) positive. Both labs would be required to be submitted.
   iii. Hepatic or renal function, or other labs that would affect the approvable quantity if impairment exists. Example: For capecitabine, if moderate renal impairment exists then the dose should be reduced by 25% per the dosage and administration section of the drug label.

4. Approval duration (one of the below):
   a. Approve for 1 cycle if the duration requested for one cycle is specific only to that drug or drug regimen and strength. Example: Capecitabine or temozolomide may be initially prescribed to be taken every day with radiation for 5 weeks. The total duration approvable would be 5 weeks. Additional cycles are typically for a different strength and duration in length.
   b. Approve for 3 months for active cancer diagnoses. Examples: Metastatic breast or prostate cancer.
   c. Approve for 6 months for cancers in remission or if maintenance therapy. Examples: Multiple myeloma or CML.

5. Approvable quantity:
   a. Initial authorizations for the first two fills will be limited to a 14 day supply (Partial-Fill) to confirm the patient has experienced an objective response to therapy and is tolerating the therapy well.

6. Continuation criteria (all must be met):
   a. Chart notes documenting a positive response to cancer therapy and no intolerable side effects.
   b. Lab work and/or radiographic evidence demonstrating a response or continued response to therapy as supported by NCCN, ASCO, or other oncology guidelines.
   Examples:
   - A decrease from baseline of PSA for prostate cancer (may need scan submitted).
   - A decrease from baseline BCR-ABL lab for CML.
   - A scan that supports no disease progression or a decreased CEA level from baseline for breast cancer.
   - A decreased from baseline of monoclonal protein, Ig levels, FLC’s (free light chains), or beta-2- microglobulin for multiple myeloma.
Non Formulary oral oncology medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Must be prescribed by an oncologist or by a mid-level clinician directly supervised by an oncologist.

2. Requested medication(s) and the diagnosis must meet either a, b, or c.

   If the request is for a regimen comprised of more than one oncology drug, including injectable or infused drugs, then the entire regimen still needs to be reviewed to meet either a, b, or c listed below.

   a. **FDA indication.** Documentation must be submitted that the requested drug or regimen meets the FDA indication(s) in full. In full is defined as following the specified indication, strength and directions, including dosing cycle if applicable, any genetic testing requirements and acknowledging any applicable black box warnings.

   b. **Compendia.** If the FDA indication is not met in full, then the request is considered off-label and must meet one of the following compendia.

      i. American Hospital Formulary Service (AHFS) Compendium.
      ii. Micromedex/DrugDex Compendium with a Class I, IIa, or IIb rating.
      iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a strong recommendation.
      v. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN) Category of 1, 2A, or 2B.

   c. **Evidence.** If the FDA indication or compendia is not met then two published, peer-reviewed, randomized, phase 3 or greater clinical trials that support the safety and efficacy of the requested drug or drug regimen and the diagnosis can be submitted for review. The clinical
trials must be consistent with the drug or drug regimen requested including the dosing and/or dosing cycle. The conclusion by the trial authors must include that it is considered safe and effective for the requested use.

Clinical Trial Phases:

- **Preclinical research**: A trial done in a lab and not tested in animals or humans.
- **Phase 0**: The first clinical trials to be done among people. In these trials a very small dose of a drug is given to about 10 to 15 people.
- **Phase I**: An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects.
- **Phase II**: An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete.
- **Phase III**: Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way.
- **Phase IV**: After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment’s risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials.

3. **Documentation required** (*ALL must be met unless indicated.*):

   a. Chart notes dated within 3 to 6 months supporting the oncology diagnosis and treatment plan. Treatment plan must include the drug or the drug regimen requested.

   b. Lab work pertaining to drug or drug regimen requested. All of the below may or may not be applicable.

      i. Genetic test lab report(s) to support a specific mutation.

      *Example:* The FDA indication for Tagrisso© requires mutation T790M be present.

      ii. Other lab report(s) to support the diagnosis.

      *Example:* The FDA indication for Ibrance© requires the patient to be HER2 negative and hormone receptor (HR) positive. Both labs would be required to be submitted.

      iii. Hepatic or renal function or other labs that would affect the approveable quantity if impairment exists.

      *Example:* For capecitabine if moderate renal impairment exists then the dose should be reduced by 25% per the dosage and administration section of the drug label.
4. **Approval duration** *(one of the below)*:
   a. Approve for one cycle if the duration requested for one cycle is specific only to that drug or drug regimen and strength.
   *Example:* *Capecitabine or temozolomide may be initially prescribed to be taken every day with radiation for 5 weeks. The total duration approved would be 5 weeks. Additional cycles are typically for a different strength and duration in length.*
   b. Approve for 3 months for active cancer diagnoses.
   *Examples:* *Metastatic breast or prostate cancer.*
   c. Approve for 6 months for cancers in remission or if maintenance therapy.
   *Examples:* *Multiple myeloma or CML.*

5. **Approvable quantity:**
   a. Initial authorizations for the first two fills will be limited to a 14 day supply (partial-fill) to confirm the patient has experienced an objective response to therapy and is tolerating the therapy well.

6. **Continuation criteria (all must be met):**
   a. Chart notes documenting a positive response to cancer therapy and no intolerable side effects.
   b. Lab work and/or radiographic evidence demonstrating a response or continued response to therapy as supported by NCCN, ASCO, the prescribing drug label or other oncology guidelines.
   *Examples:*
   - A decrease from baseline of PSA for prostate cancer *(may need scan also submitted).*
   - A decrease from baseline BCR-ABL lab for CML.
   - A scan that supports no disease progression or a decreased CEA level from baseline for breast cancer.
   - A decreased from baseline of monoclonal protein, IG levels, FLC’s *(free light chains)*, or beta-2-microglobulin for multiple myeloma.

References:
Criteria created 9/2017; Last reviewed March 2019
Orencia is a self-administered subcutaneous injection that is a selective T cell costimulation modulator indicated for:

- Moderately to severely active rheumatoid arthritis in adults as monotherapy or concomitantly with DMARDs other than TNF antagonists.
- Moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older as monotherapy or concomitantly with methotrexate.
- Active psoriatic arthritis in adults.

Orencia will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or provider attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Hydroxychloroquine
      iii. Sulfasalazine
      iv. Leflunomide
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of, both Humira (adalimumab) and Enbrel (etanercept).
   g. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of at least three of the following:
      • Olumiant (baricitinib)
      • Kevzara (sarilumab)
      • Actemra (tocilizumab)
      • Cimzia (certolizumab)
h. Requested dose and dosing interval is consistent with the FDA labeled recommended dosing for Orencia.
   i. Documentation Orencia will be self-administered by the member by subcutaneous injection.

2. **Polyarticular juvenile idiopathic arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age of member is ≥ 2 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of moderate to severe arthritis with at least five swollen joints and at least three joints with limitation of motion.
   e. Trial and failure of one of the following therapies unless intolerant or contraindicated
      i. Methotrexate for at least 30 days
      ii. Oral NSAID for at least 30 days
      iii. Oral corticosteroid for at least 14 days
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both **Humira** (adalimumab) and **Enbrel** (etanercept).
   g. Requested dose and dosing interval is consistent with the FDA labeled recommended dosing for Orencia and with the current weight (within 30 days) of the member.
   h. Documentation Orencia will be self-administered by the member by subcutaneous injection.

3. **Psoriatic arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe psoriatic arthritis per chart notes or prescriber attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Leflunomide
      iii. Sulfasalazine
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both **Humira** (adalimumab) and **Enbrel** (etanercept).
   g. Documentation submitted supporting Orencia will be self-administered by the member at a maintenance dose of 50 mg and dosing interval of no less than every 4 weeks.

**Approval Length:** Three months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits:** Up to four prefilled syringes per 30 days.

**Continuation Criteria:**

*Rheumatoid arthritis* and *psoriatic arthritis* – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.
Polyarticular juvenile idiopathic arthritis – Documentation submitted supporting member has achieved and is maintaining a 30% improvement in number of joints with active arthritis and the number of joints with limitation of movement.

For all diagnoses: If member is transitioning to the subcutaneous injection formulation from intravenous infusion then all initial pharmacy benefit criteria must be met in full.

Exclusions:
1. Concomitant use with other biologic DMARD medications (oral and injectable).
2. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:

Criteria updated: 5/2019
Orilissa is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

Recommended dosing for Orilissa:

If normal liver function or mild hepatic impairment: 150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months in patients who also have dyspareunia.

If moderate hepatic impairment: 150 mg once daily for up to 6 months.

**ORILISSA** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by, or in consultation with a gynecologist.
2. Member is 18 years of age or older.
3. Documented diagnosis of endometriosis confirmed by laparoscopy or laparotomy or if surgical diagnosis is contraindicated, by transvaginal ultrasonography.
4. Documented trial of at least 90 days and failure, defined as no relief of symptoms, of both of the following in the past 12 months:
   i. One oral NSAID medication unless documented contraindication.
   ii. One continuous hormonal contraceptive unless documented contraindication or norethindrone for members who cannot use estrogen therapy.
      Formulary continuous hormonal contraceptives:
      - Medroxyprogesterone acetate IM injection, Ashlyn, Amethia, Amethia Lo, Camrese, Camrese Lo, Daysee, Introvale, Jolessa, Setlakin, and Quasense.
   iii. Documented trial and failure of, or contraindication to, levonorgestrel IUD (Mirena, Kyleena). Failure is defined as no improvement in symptoms.
5. For treatment of endometriosis, request is for 150mg daily for up to 24 months for a member with normal or mild hepatic impairment. For members with moderate hepatic impairment, request is for 150mg daily for up to maximum 6 months.
6. For treatment of endometriosis with dyspareunia, request is for 200mg twice daily for up to 6 months for a member with normal or mild hepatic impairment. The use of 200mg is not recommended for moderate hepatic impairment.
7. Prescriber attestation that member does not have severe hepatic impairment.

**Approval Length:**
*Orilissa 200 mg* - Three months initially then an additional three months to complete the treatment course. Maximum of 6 months total of treatment.
**Orilissa 150 mg** – If normal or mild hepatic impairment, 3 months initially and up to 6 months for reauthorizations for a total duration of 24 months. For moderate hepatic impairment, three months initially then an additional three months to complete the treatment course with a maximum of 6 months total of treatment.

**Quantity Limits:**
150mg tablets: 30 tablets per 30 days (one tablet a day).
200mg tablets: 60 tablets per 30 days (one tablet twice daily).

**Continuation Criteria:**
1. Documentation submitted supporting positive response is occurring demonstrated by a decrease in pain symptoms per chart notes and no increase in analgesic use (narcotic and NSAID)

**Exclusions:**
1. Known diagnosis of osteoporosis.
2. Severe impairment hepatic (Child-Pugh Class C).
3. Concomitant use with Lupron-Depot.

**References:**

Criteria updated 6/2019
Otezla® is an inhibitor of phosphodiesterase 4 (PDE4) and indicated for the treatment of:

- Adult patients with active psoriatic arthritis
- Patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

Otezla® will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Psoriatic Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documented diagnosis of **moderate to severe** psoriatic arthritis per chart notes or prescriber attestation.
   d. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Hydroxychloroquine
      iii. Sulfasalazine
      iv. Leflunomide
   e. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira® (adalimumab) and Enbrel® (etanercept).

2. **Plaque Psoriasis (Adult)**
   a. Prescribed by or in consultation with a dermatologist or rheumatologist.
   b. Age ≥ 18 years.
   c. Documented diagnosis of **moderate to severe** plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
      
      **Note:** An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.
   d. Documentation member has failed topical therapy for a trial of at least 90 days and includes two of the following verified by prescription claims history:
      i. Calcipotriene (generic Dovonex) topical preparations
      ii. Medium-to-high potency corticosteroids
         
         **Note:** For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
      iii. Tazorac topical gel 0.05%
      iv. Tacrolimus 0.1% (prior authorization required) ointment
v. Coal tar preparations such as coal tar shampoo

e. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
   i. Methotrexate oral tablets
   ii. Cyclosporine oral capsules

f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).

3. Oral Ulcers due to Behcet’s Disease

   i. Documented diagnosis of Behcet’s disease
   ii. 12 week trial and failure of, or contraindication to ALL of the below:
       • intra-oral topical steroids
       • colchicine
       • one or more of the following:
         1. azathioprine
         2. thalidomide
         3. interferon-alpha
       • Humira (tumor necrosis factor-alpha inhibitor)
       • one or more of the following:
         1. systemic dapsone
         2. azithromycin

Approval Length: Three months initially then up to 12 months thereafter based on clinical response.

Quantity Limits (applicable for both indications):

Initial dosing – One Otezla starter therapy pack to last 30 days in duration.

Maintenance dosing – Up to 60 tablets per 30 days of the 30 mg tablet strength only.

Continuation Criteria:

Psoriatic arthritis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters

Psoriasis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters based on decreased total percent BSA affected.

Exclusions:

1. Needle phobia is not considered a clinical reason for the use of Otezla instead of the required alternatives unless it meets DSM-V-TR 300.29 (Specific Phobia).

2. Concomitant use with other biologic DMARD medications (oral and injectable).

3. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.

4. The following is a list of acceptable contraindications for the use of methotrexate:
• Pregnancy
• Actively breast-feeding
• Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
• Immunodeficiency syndrome
• Hepatitis B or C infection
• Liver enzymes that are persistently elevated
• Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

References:

Criteria updated: 5/2019
Pulmonary hypertension (PH) is defined as a pulmonary artery pressure ≥25 mmHg. PH World Health Organization (WHO) Group 1 is defined as pulmonary arterial hypertension (PAH), the specific etiologies of which are defined by the WHO. *(Appendix A)*

Generic sildenafil (Revatio) and Adcirca tablets are phosphodiesterase 5 (PDE5) inhibitors indicated for the treatment of PAH WHO Group 1 in adults to improve exercise ability.

Tracleer tablets and Letairis tablets are endothelin receptor antagonists (ERAs) indicated for the treatment of PAH WHO Group 1 to improve exercise ability and delay clinical worsening. Tracleer is also indicated for use in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR) which is expected to improve exercise ability. Letairis is indicated for use in combination with Adcirca.

Remodulin is a prostacyclin analog indicated for the treatment of PAH WHO Group 1 to diminish symptoms associated with exercise. It is administered by continuous infusion either subcutaneously (SC) or intravenously if the SC route is not tolerated. SC route is accomplished with a microinfusion pump and catheter.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>REVATIO</td>
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<td>TRACLEER</td>
<td>bosentan</td>
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<td>LETAIRIS</td>
<td>ambrisentan</td>
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<td>REMODULIN</td>
<td>treprostinil</td>
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### CRITERIA FOR COVERAGE/NON-COVERAGE

<table>
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<tr>
<th></th>
<th>Indicated for PAH WHO Group 1</th>
<th>Indicated to improve exercise</th>
<th>Indicated for idiopathic or congenital PAH in pediatric (≥3yr.old) patients</th>
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<td>PDE5s</td>
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<tr>
<td>sildenafil</td>
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<td>Adcirca</td>
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<td></td>
<td>Letairis</td>
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<tr>
<td>Prostacyclin analogs</td>
<td>Remodulin</td>
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</table>
The above medications will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The request is prescribed by a cardiologist or pulmonologist experienced in the diagnosis and treatment of pulmonary hypertension.
2. The member is at least 18 years of age. For Tracleer, the member must be aged 3 years or older.
3. The member has a diagnosis of PAH WHO Group 1 and both of the following are met:
   a. One of the following:
      i. A negative vasoreactivity test
      ii. A contraindication to vasoreactivity testing (i.e. low systemic blood pressure, low cardiac index, or the presence of severe (functional class IV) symptoms), OR
      iii. A positive vasoreactivity test with trial and failure of a calcium channel blocker,
      iv. Contraindication to the use of a calcium channel blocker
   b. Documentation affirming that the diagnosis was confirmed by right heart catheterization or by Doppler echocardiogram.
4. The following criteria are met for each respective requested medication:

**Sildenafil 20mg tablets**
1. Documentation member has New York Heart Association (NYHA) Functional Classification II-IV heart failure.
2. Member is currently not on nitrate therapy such as isosorbide or nitroglycerin.
3. Member will not be concurrently taking a guanylate cyclase stimulator such as riociguat (Adempas).

**Adcirca tablets**
1. Documentation member is NYHA Class II-IV
2. The member must have tried and failed or have a documented intolerance to a 30 day trial of sildenafil
3. Member is currently not on nitrate therapy such as isosorbide or nitroglycerin.
4. Member will not be concurrently taking a guanylate cyclase stimulator such as riociguat (Adempas).

**Tracleer tablets**
1. Documentation member is NYHA Class II- IV.
2. Baseline hepatic labs have been submitted supporting no moderate or severe hepatic impairment.

**Letairis tablets**
1. Documentation member is NYHA Class II-IV.
2. Baseline hepatic labs have been submitted supporting no moderate or severe hepatic impairment.

**Remodulin injection**

1. **One** of the following is met:
   a. Documentation member is NYHA Class II and has tried and failed or has a documented intolerance to a 30 day trial of **sildenafil, Adcirca, Letairis and Tracleer**.
   b. Documentation member is NYHA Class III or IV.

   **Note:** The World Symposium on Pulmonary Hypertension (WSPH) updated treatment algorithm for PAH recommends the use of subcutaneous Remodulin and intravenous Remodulin in patients WHO Functional Class III or Class IV. Patients in Functional Class II should be treated with an oral agent for PAH (e.g., Tracleer, Opsumit, Letairis, Adempas, sildenafil, Adcirca).

2. If the request is for the intravenous route of administration then documentation has been submitted supporting failure or intolerance to the subcutaneous use of Remodulin.

   **Note:** Per the Remodulin FDA prescribing information, due to the risks associated with chronic indwelling central venous catheters, including serious blood stream infections (BSIs), reserve continuous intravenous infusion for patients who are intolerant of the subcutaneous route, or in whom these risks are considered warranted.

**Approval Length:** If criteria are met, the authorization is for 6 months initially and 12 months for renewals.

**Quantity Limits:**

- **Sildenafil** – Up to 90 tablets per 30 days
- **Adcirca** – Up to 60 tablets per 30 days
- **Tracleer** – Up to 60 tablets per 30 days. Not to exceed 125mg twice daily.
- **Letairis** – 30 tablets per 30 days
  - **Remodulin** – The dose is weight-based and titrated to efficacy and tolerability therefore the appropriate number of vials should be calculated based on the current weight submitted and the requested dose.

**Continuation Criteria:** Authorization for continued use shall be reviewed at least every 12 months to confirm the use of the medication. Recent chart notes are required for review and may include any of the following listed below.

- 6-minute walk distance (6MWD)
• O₂ saturation levels
• Other hemodynamic and clinical notes and/or labs.

**Note:** Interruptions of PAH therapy may lead to worsening of PAH symptoms and other consequences therefore members transitioning to Health Choice from another health plan (or other type of payer) and are previously established on any PAH therapy will be allowed a one month transition approval.

**APPENDIX A**

**WHO Pulmonary Hypertension (PH) Group Classification:**

**Group 1: Pulmonary arterial hypertension (PAH)**
1. Idiopathic PAH (IPAH)
2. Heritable PAH
3. Drug and toxin-induced
4. Associated with (APAH)
   1.1. Connective tissue disease
   1.2. HIV infection
   1.3. Portal hypertension
   1.4. Congenital heart diseases
   1.5. Schistosomiasis
   1.6. Chronic hemolytic anemia
   1.7. Persistent pulmonary hypertension of the newborn (PPHN)

**Group 2: PH due to left heart disease**

**Group 3: PH due to lung diseases and/or hypoxia**

**Group 4: Chronic thromboembolic PAH (CTEPH)**

**Group 5: Miscellaneous/PAH with unclear multifactorial mechanisms**

**WHO functional classification of PAH (modified after NYHA functional classification):**

**Class I:** No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.

**Class II:** Slight limitation of physical activity. Comfortable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.

**Class III:** Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.

**Class IV:** Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.

**References:**

Criteria created March 2018; Last revised Sept 2019
Pulmonary hypertension (PH) is defined as a pulmonary artery pressure ≥25 mmHg. PH World Health Organization (WHO) Group 1 is defined as pulmonary arterial hypertension (PAH), the specific etiologies of which are defined by the WHO. (Appendix A)

**Opsumit** is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH) WHO Group I to delay disease progression. Disease progression defined as death, initiation of intravenous (IV) or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). Opsumit has also been shown to reduce hospitalization for PAH.

**Adempas** is a soluble guanylate cyclase (sGC) stimulator indicated for the treatment of adults with:

- Persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class.

- PAH WHO Group 1 to improve exercise capacity, improve WHO functional class, and to delay clinical worsening.

**Uptravi** is a prostacyclin receptor agonist indicated for the treatment of PAH WHO Group 1 to delay disease progression and reduce the risk of hospitalization for PAH.

**Orenitram** is a prostacyclin vasodilator indicated for the treatment of PAH WHO Group 1 to improve exercise capacity.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>OPSUMIT</td>
<td>macitentan</td>
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<td>ADEMPAS</td>
<td>riociguat</td>
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<tr>
<td>UPTRAVI</td>
<td>selexipag</td>
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<td>ORENNITRAM</td>
<td>treprostinil tablets</td>
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<tr>
<td>TYVASO</td>
<td>treprostinil</td>
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<tr>
<td>VENTAVIS</td>
<td>iloprost</td>
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<tr>
<td>FLOLAN</td>
<td>epoprosthenol</td>
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</table>
**Tyvaso and Ventavis** are both prostacyclin analogs and indicated for the treatment of PAH WHO Group 1 to improve exercise ability. Tyvaso and Ventavis are inhaled by nebulization.

**Generic epoprostenol (Flolan)** is a prostacyclin analog indicated for the treatment of PAH WHO Group 1 to improve exercise capacity. It is administered by continuous intravenous infusion via a central venous catheter using an ambulatory infusion pump.

The above medications will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The request is prescribed by a cardiologist or pulmonologist experienced in the diagnosis and treatment of pulmonary hypertension.
2. The member is at least 18 years of age.
3. The member has a diagnosis of PAH WHO Group 1 (except if request for Adempas WHO Group 4) with:
   a. One of the following:
      i. A negative vasoreactivity test
      ii. A contraindication to vasoreactivity testing (i.e. low systemic blood pressure, low cardiac index, or the presence of severe (functional class IV) symptoms)
      iii. A positive vasoreactivity test with trial and failure of a calcium channel blocker
      iv. Contraindication to the use of a calcium channel blocker
   b. Documentation affirming that the diagnosis was confirmed by right heart catheterization or by Doppler echocardiogram.
4. The following criteria are met for each respective requested medication:

**Opsumit**

1. Documentation member is NYHA class II-IV
2. Documented treatment failure, intolerance, or contraindication to sildenafil and Adcirca.
3. Documented treatment failure, intolerance, or contraindication Tracleer and Letairis.
4. Documented treatment failure, intolerance, or contraindication to a formulary prostacyclin analog, if clinically applicable per the patient’s NYHA functional class.

**Adempas**

1. Diagnosis meets either a. or b. below.
   a. WHO Group 1 PAH AND NYHA class II-IV AND meets criteria diagnostic criteria previously described in this policy for WHO Group 1 PAH
   b. WHO Group 4 and CTEPH (chronic thromboembolic pulmonary hypertension) that is inoperable or persistent (i.e. suboptimal surgical outcome)
2. If **WHO Group 1 PAH** diagnosis *all* of the following must be met:
   a. Documented treatment failure, intolerance, or contraindication to sildenafil and Adcirca.
   b. Documented treatment failure, intolerance, or contraindication to Tracleer and Letairis.
   c. Documented treatment failure, intolerance, or contraindication to a formulary prostacyclin analog, if clinically applicable per the patient’s NYHA functional class.

3. If **CTEPH** diagnosis *all* of the following must be met:
   a. Member has persistent or recurrent pulmonary hypertension after at least 180 days following surgical treatment with pulmonary endarterectomy or Inoperable (via pulmonary endarterectomy) CTEPH.
   b. Member has NYHA Class II-IV.

**Uptravi**

1. Documentation submitted that the member has NYHA class II-IV.
2. Documented treatment failure, intolerance, or contraindication to sildenafil and Adcirca.
3. Documented treatment failure, intolerance, or contraindication to Tracleer and Letairis.
4. Documented treatment failure, intolerance, or contraindication to a formulary prostacyclin analog, if clinically applicable per the patient’s NYHA functional class.
5. Baseline hepatic labs and notes supporting patient does not have severe hepatic impairment defined by a recent Child-Pugh score.

**Orenitram**

1. Documentation member has NYHA class II-IV.
2. Documented treatment failure, intolerance, or contraindication to sildenafil AND Adcirca.
3. Documented treatment failure, intolerance, or contraindication to Tracleer AND Letairis.
4. Documented treatment failure, intolerance, or contraindication to a formulary prostacyclin analog, if clinically applicable per the patient’s NYHA functional class.

**Ventavis or Tyvaso inhalation**

1. Documentation member is NYHA Class III-IV.

**Epoprostenol injection**

1. Documentation member is NYHA Class II and has tried and failed or has a documented intolerance to a 30 day trial of sildenafil, Adcirca, Letairis and Tracleer.

2. Documentation member is NYHA Class III-IV.

*Note: The World Symposium on Pulmonary Hypertension (WSPH) updated treatment algorithm for PAH recommends the use of intravenous epoprostenol in patients WHO Functional Class III or Class IV. Patients in NYHA Functional Class II should be treated with an oral agent for PAH (e.g., Tracleer, Opsumit, Letairis, Adempas, sildenafil, Adcirca).*
Continuous intravenous epoprostenol is recommended first-line for patients in NYHA Functional Class IV because of the survival benefit in this subset.

**Approval Length:** If criteria are met, the authorization is for 6 months initially and 12 months for renewals.

**Quantity Limits:**
- **Opsumit** – 30 tablets for 30 days. Doses higher than 10mg daily have not been studied and are not recommended.
- **Adempas** – Up to 90 tablets per 30 days
- **Uptravi** – Up to 1600 mcg twice daily
- **Orenitram** – Up to 90 tablets per 30 days
- **Ventavis** – Nine ampules per day
- **Tyvaso** – one ampule per day
- **Epoprostenol** – The dose is weight based and titrated to efficacy and tolerability therefore the appropriate number of vials should be calculated based on the current weight submitted and the requested dose.

**Continuation Criteria:** Authorization for continued use shall be reviewed at least every 12 months to confirm the use of the medication. Recent chart notes are required for review and may include any of the following listed below.
- 6-minute walk distance (6MWD)
- O2 saturation levels
- Other hemodynamic and clinical notes and/or labs.

**Note:** Interruptions of PAH therapy may lead to worsening of PAH symptoms and other consequences therefore members transitioning to Health Choice from another health plan (or other type of payer) and are previously established on any PAH therapy will be allowed a one month transition approval.

**Exclusions:**
- **Opsumit** will not be approved if the member has any of the following:
  - Member is initiating therapy and has a diagnosis of clinically significant anemia
  - Is being used in combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Tracleer (bosentan).
  - Is being used in combination with oral treprostinil (Orenitram)
  - Raynaud’s phenomenon, with or without digital ulcers

- **Adempas** will not be approved if the member has any of the following:
  - A diagnosis of severe hepatic impairment (Child-Pugh Class C)
  - Is on dialysis or has a creatinine clearance less than 15 mL/min;
- Has a diagnosis of pulmonary veno-occlusive disease (PVOD)
- Has a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP)
- Use in combination with phosphodiesterase (PDE) inhibitors [such as, PDE-5 inhibitors (sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (dipyridamole, theophylline)]
- Use in combination with nitrates (such as but not limited to, nitroglycerin) or nitric oxide donors (such as but not limited to, amyl nitrite) in any form.

**Uptravi** will not be approved if the member has any of the following:
- Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C)
- In combination with prostacyclin analogs [such as but not limited to treprostinil (Orenitram, Remodulin, Tyvaso), epoprostenol (Flolan, Venetis), Ventavis (iloprost)]
- Individual is on dialysis or a glomerular filtration rate less than 15 mL/min/1.73 m².
- Digital ischemia and/or ulcers, including Raynaud’s phenomenon, due to systemic sclerosis, scleroderma or other causes.

**APPENDIX A**

**WHO Pulmonary Hypertension (PH) Group Classification:**

Group 1: Pulmonary arterial hypertension (PAH)

1.1. Idiopathic PAH (IPAH)
1.2. Heritable PAH
1.3. Drug and toxin-induced
1.4. Associated with (APAH)
   1.4.1. Connective tissue disease
   1.4.2. HIV infection
   1.4.3. Portal hypertension
   1.4.4. Congenital heart diseases
   1.4.5. Schistosomiasis
   1.4.6. Chronic hemolytic anemia
1.5. Persistent pulmonary hypertension of the newborn (PPHN)

Group 2: PH due to left heart disease

Group 3: PH due to lung diseases and/or hypoxia

Group 4: Chronic thromboembolic PAH (CTEPH)

Group 5: Miscellaneous/PAH with unclear multifactorial mechanisms

**WHO functional classification of PAH (modified after NYHA functional classification):**

Class I: No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.

Class II: Slight limitation of physical activity. Comfortable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.

Class III: Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.

Class IV: Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.

**References:**


Criteria created March 2018; Revised Sept 2019
**Brand Name** | **Generic Name**
---|---
Pegasys® | Peginterferonalpha-2a
Pegintron® | Peginterferonalpha-2b

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Pegasys/Pegintron** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member must be clinically diagnosed with one of the following conditions and meet individual criteria if stated:

1. **Chronic hepatitis C with compensated liver disease and meets either (a) or (b) below:**
   
   a. **Combination therapy request** (either (i.) or (ii.) below):
      
      i. **For genotype 1 infections:** Member is using in combination with ribavirin and an NS3/4A protease inhibitor unless there are contraindications to NS3/4A inhibitor use.
      
      ii. **For adult patients with HCV genotypes other than 1 and pediatric patients (3-17 years old):** Member is using in combination with ribavirin
   
   b. **Monotherapy request:**
      
      i. **Member is 18 years of age or older and has contraindication or significant intolerance to ribavirin and has not been previously treated with interferon alfa.**

   **NOTE:** Peginterferon regimens are no longer recommended in the HCV treatment guidelines.

2. **Pegasys only:** Chronic hepatitis B (HBsAg positive for at least 6 months) and meets either (a) or (b) below:
   
   a. **Member is 3 years of age or older:**
      
      i. **Member is HBeAg positive and noncirrhotic**
      
      ii. **Member has evidence of viral replication and elevations of alanine aminotransferase**
   
   b. **Member is 18 years of age or older**
      
      i. **Member is either HBeAg positive or negative with compensated liver disease**
      
      ii. **Member has evidence of viral replication and liver inflammation**

**Exclusions:**

1. **Member has uncontrolled depression**
2. **Member has autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon and ribavirin**

**Approval Length:** Will be determined based on diagnosis and patient type.
References
Criteria last reviewed and updated: 04/2019
**Non-Formulary**

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<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEXEVA</td>
<td>Paroxetine mesylate</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**PEXEVA** a selective serotonin reuptake inhibitor and is indicated for the following:

- The treatment of MDD.
- The treatment of obsessions and compulsions in patients with obsessive-compulsive disorder (OCD)
- The treatment of panic disorder (PD), with or without agoraphobia,
- The treatment of Generalized Anxiety Disorder (GAD),

**PEXEVA** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- A documented diagnosis of MDD, OCD, PD, or GAD.
- The member is over the age of 18 years old.
- A documented trial evidenced by prescription claims history of at least 30 days and failure of or intolerance supported by chart notes to **all** of the following formulary alternatives: Escitalopram, citalopram, fluoxetine, fluvoxamine (including extended-release), paroxetine (including extended-release), sertraline, venlafaxine (including extended-release), duloxetine (20, 30, and 60 mg), desvenlafaxine, bupropion, and mirtazapine.

**Approval Length:** 12 months.

**Continuation criteria:**

1. Documentation member is receiving a positive clinical response.

**References:**


Criteria last updated 04/2019
**Covered Product**

<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Reference Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>pimecrolimus</td>
<td>ELIDEL 1% CREAM</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Pimecrolimus 1% Cream** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. *Age* 2 years and older  
2. Member has diagnosis of:  
   a. Atopic Dermatitis (eczema)  
   b. Vulvar Lichen Sclerosus  
   c. Psoriasis  
   d. Vitiligo (on head or neck)

Member has tried and failed an adequate course of therapy with TWO formulary medium to high potency topical corticosteroids OR Member has contraindication to medium to high potency topical corticosteroids (e.g., areas involving eyelids, face, or genital areas)

Formulary covers 30gm/30days. Documentation supporting necessity of additional quantity.

**Initial approval duration:** 12 months.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

**Very High Potency:**

augmented betamethasone 0.05% (Diprolene) ointment, gel, lotion  
clobetasol propionate 0.05% (Temovate) cream, ointment  
halobetasol propionate 0.05% (Ultravate) cream, ointment

**High Potency:**

augmented betamethasone 0.05% (Diprolene)cream  
diflorasone 0.05% (Psorcone E, Florone) cream, ointment  
fluocinonide acetonide 0.05% (Lidex)cream, ointment, gel, solution  
triamcinolone acetonide 0.5% (Aristocort, Kenalog) cream, ointment
Medium Potency:
desoximetasone 0.05% (Topicort) cream, ointment, gel
fluocinolone acetonide 0.025% (Synalar) cream, ointment
mometasone 0.1%(Elocon) cream, ointment, lotion
triamcinolone acetonide 0.025%, 0.1% (Aristocort, Kenalog) cream, ointment

Low Potency:
aclometasone 0.05% (Aclovate) cream, ointment
desonide 0.05% (Desowen cream, ointment, lotion
fluocinolone acetonide 0.01% (Synalar) solution
hydrocortisone 2.5% (Hytone) cream, ointment

References

Criteria last reviewed and updated: 02/2019
Non-Formulary PCSK 9 Agent - Brand Name (Generic)

PRALUENT (alirocumab)

**CRITERIA FOR COVERAGE/NONCOVERAGE**

The recommended starting dose of PRALUENT is 75 mg once every 2 weeks administered SQ, since the majority of patients achieve sufficient LDL-C reduction with this dosage. An alternative starting dosage for patients who prefer less frequent dosing is 300 mg once every 4 weeks (monthly).

**PCSK 9 Inhibitors** will be considered for coverage under the pharmacy benefit when the following criteria are met:

**Criteria for Initial Therapy:**

1. Member must be ≥ 18 years of age

2. Must be prescribed by, or in with, a cardiologist, endocrinologist, or lipid specialist

3. Must have clinical documentation of ONE of the following diagnoses:
   
   a. Must have diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by one of the following:
      
      i. Diagnosis confirmed by DNA-based evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation

      ii. Diagnosis confirmed by clinical criteria as “definite FH” using WHO/Dutch Lipid Network with a score 9 or higher using the WHO/Dutch Lipid Network criteria

      iii. Diagnosis confirmed by clinical criteria using Simon Broome criteria with a total cholesterol > 290mg/dL or LDL cholesterol > 190mg/dL AND tendon xanthomas in patient, or in 1st degree relative (parent, sibling, child), or in 2nd degree relative (grandparent, uncle, aunt)

   b. Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:
      
      i. Acute coronary syndromes

      ii. History of myocardial infarction

      iii. Stable or unstable angina

      iv. Coronary or other arterial revascularization

      v. Stroke

      vi. Transient ischemic attack

      vii. Peripheral arterial disease presumed to be of atherosclerotic origin

4. Appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment, supported by documentation of counseling in chart notes

   a. Total dietary fat < 35% of total calories

   b. Weight loss in overweight patients
c. Aerobic exercise
d. Diet rich in fruits and vegetables

5. Baseline and current LDL-C is provided
6. Require additional LDL-C reduction after 90-day trial of a high-intensity statin at maximum dosage (atorvastatin 80mg or rosuvastatin 40mg) in combination with ezetimibe. Additional LDL-C reduction defined as an inadequate response to therapy by not achieving ≤ 50% reduction in LDL-C from baseline or LDL-C is ≥ 100 mg/dL with ASCVD or is ≥ 130 mg/dL without ASCVD
7. Contraindication/intolerance to a high intensity statin defined as ONE of the following:
   a. A labeled contraindication to all statins as documented in medical records
   b. Member has experienced documented rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN
   c. Member has undergone a trial of a statin rechallenge (i.e. pravastatin 10-40 mg or rosuvastatin 5 mg) with documented reappearance of muscle symptoms such as myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks)
   d. Member is unable to tolerate low-, moderate-, and high-intensity statins as evidenced by documented myalgia or myositis that is intolerable and persistent (i.e., more than 2 weeks)
8. Patient has been adherent to lipid-lowering therapy, defined as proportion of days covered (PDC) ≥ 80%
9. Will be used in combination with a maximally tolerated statin

Criteria for Continuing Therapy:

A. Current LDL-C level provided to assess response to medication
B. Documentation supports a sustained LDL-C reduction from pre-treatment baseline (e.g., prior to Praluent therapy) while on Praluent therapy.
C. The member is tolerating the medication
D. Medication will continue to be used in combination with a maximally tolerated statin
E. Patient has remained adherent to statin therapy, defined as proportion of days covered (PDC) ≥ 80%

Authorization for Initial approval: 3 months and renewal approval: One year

Quantity Limit: 2/28 days

References:


Last reviewed and updated: 6/2019
Pregabalin will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Partial-onset seizures: as adjunctive therapy of partial-onset seizures in patients 18 years of age and older.
   a. Member has tried and failed at least 2 generically available anticonvulsants

2. Fibromyalgia
   a. Member has tried and failed duloxetine (generic Cymbalta) at maximum tolerated dose or dose up to 60mg/day for at least 90 days

3. Neuropathic pain associated with diabetic peripheral neuropathy
   a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.

4. Neuropathic pain associated with spinal cord injury
   a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.

5. Postherpetic neuralgia
   a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.

Quantity Level Limits:
1. For the following strengths: 25mg/50mg75mg/100mg/150mg/200mg, QL is #90 every 30 days
2. For the following strengths: 225mg/300mg, QL is #60 every 30 days

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References

Criteria last reviewed and updated: 6/2019
Prevymis is a CMV DNA terminase complex inhibitor indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

The recommended dose is a 480 mg tablet taken once a day up until 100 days post-transplant.

If co-administered with cyclosporine the dosage should be decreased to 240 mg once daily.

Prevymis will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member is 18 years of age or older.
2. Prescribed by, or in consultation with an oncologist/hematologist, infectious disease, or transplant specialist.
3. Documentation has been submitted supporting the member is CMV-seropositive.
4. Documentation has been submitted supporting the member recently (within 28 days) underwent an allogeneic hematopoietic stem cell transplant.
5. Documentation the member does not have CMV viremia (reactivation).
6. Documentation submitted supporting the member does not have Child-Pugh Class C hepatic impairment.

Approval Length: Up until 100 days post-transplantation with consideration of utilization occurring during inpatient hospital stay, if applicable.

Quantity Limits: Maximum of one tablet daily of either the 480 mg tablet or 240mg tablet.

Exclusions:
1. Autologous stem cell transplant recipient.
2. Concomitant use with pimozide, ergot alkaloids such as ergotamine and dihydroergotamine, or when either pitavastatin or simvastatin are co-administered with cyclosporine.
3. Initiation of therapy after day 28 of transplant.
4. Treatment beyond day 100 following transplant.

References:
1. Prevymis prescribing information. Whitehouse Station, NJ; Merck & Co.; Rev Nov 2017

Criteria last reviewed/updated: 6/2019
Promacta is a thrombopoietin receptor agonist indicated for the treatment of:

- Thrombocytopenia in adult and pediatric patients 1 year and older with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.

- Thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.

- Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Promacta will be considered for coverage under the pharmacy benefit program when the following criteria are met:

**Chronic immune (idiopathic) thrombocytopenia purpura (ITP)**

1. Prescribed by, or in consultation with, a hematologist.
2. Documentation submitted supporting the member is clinically diagnosed with chronic immune thrombocytopenia. “Chronic” defined as 12 months or longer.
3. Member is age 1 year or older.
4. Documentation of trial and failure of, intolerance to, or contraindication, to one of the following:
   - Corticosteroids such as oral prednisone or dexamethasone
   - Intravenous immunoglobulin (IVIG) or Anti-Rh(D)
   - Splenectomy or is not a surgery candidate
5. Documentation the member has an increased risk for bleeding or has bleeding symptoms present.
6. Baseline lab documentation of platelet count that is low (< 30,000/µL).
7. Baseline hepatic lab documentation is submitted and the requested dosing is consistent with hepatic function.

**Severe aplastic anemia**

1. Prescribed by or in consultation with a hematologist.
2. Documented diagnosis of severe aplastic anemia and at least two of the following are submitted by lab documentation:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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</thead>
<tbody>
<tr>
<td>PROMACTA tablets, oral suspension</td>
<td>Eltrombopag</td>
</tr>
</tbody>
</table>
3. Member is 18 years of age or older.

4. Member has a documented insufficient response, or documented intolerance or contraindication, to immunosuppressive therapy with one of the following:
   - Antithymocyte globulin with Cyclosporine with or without a corticosteroid
   - Antithymocyte globulin [Thymoglobulin, Atgam] with or without a corticosteroid
   - Antithymocyte globulin with Cyclophosphamide with or without a corticosteroid
   - Cyclosporine with cyclophosphamide
   - Cyclophosphamide

5. Baseline lab documentation of platelet count that is low (< 30,000/µL).

6. Baseline hepatic lab documentation is submitted and the requested dosing is consistent with hepatic function.

**Approval Length:** Three months initially then every 6 months thereafter based on clinical response.

**Quantity Limits:**

**Chronic immune (idiopathic) thrombocytopenia purpura (ITP)** - Up to #30 tablets per 30 days (one tablet daily) and not exceeding 75 mg/day. The daily dose is to be adjusted to achieve and maintain a platelet count > 50,000/µL in order to reduce the risk for bleeding. For oral suspension, once a day dosing not exceeding 75 mg/day and documentation submitted must support inability to take oral tablets either by young age or other conditions such as dysphagia.

**Severe aplastic anemia** - Up to #30 per 30 days not exceeding 150 mg/day. The daily dose is to be adjusted to achieve and maintain a platelet count > 50,000/µL in order to reduce the risk for bleeding. For oral suspension, once a day dosing not exceeding 150 mg/day and documentation submitted must support inability to take oral tablets either by young age or other conditions such as dysphagia.

**Continuation Criteria:**

**Chronic immune (idiopathic) thrombocytopenia purpura (ITP)**

1. Documentation submitted supporting a response to treatment with a platelet count of at least 50,000/µL but less than 200,000/µL. (Response rates should be seen at least 1 week after initiation of treatment with a maximum response seen at 2 weeks).

2. Documentation submitted supporting absence of unacceptable toxicity or adverse reactions from the drug. Examples include elevated liver enzymes or thrombotic/thromboembolic complications. If any are present then documentation has been submitted addressing these toxicities and adverse reactions.

**Severe aplastic anemia**

1. Documentation submitted supporting a response to treatment by meeting one of the following criteria:
   - Platelet count increase of at least 20,000/mcl above baseline, or stable platelet counts with transfusion independence for a minimum of 8 weeks
   - Hemoglobin increase by greater than 1.5 g/dl or reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks
• ANC increase of 100% or an ANC increase greater than 500/mcl

2. Documentation submitted supporting absence of unacceptable toxicity or adverse reactions from the drug. Examples include elevated liver enzymes or thrombotic/thromboembolic complications. If any are present then documentation has been submitted addressing these toxicities and adverse reactions.

Exclusions:
1. Promacta being used in an attempt to only normalize platelet counts. The goal of treatment is to prevent bleeding and to achieve a safe, but not necessarily normal, platelet count.
2. Combination use with romiplostim (Nplate).
3. Promacta use more than once a day dosing.
4. Use of Promacta for thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.

References:

Criteria effective: 10/01/2018
<table>
<thead>
<tr>
<th>Nonformulary</th>
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<tbody>
<tr>
<td><strong>Brand Name</strong></td>
</tr>
<tr>
<td>PROZAC WEEKLY</td>
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</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**PROZAC delayed release weekly** is a selective serotonin reuptake inhibitor indicated for major depressive disorder (MDD) in those patients whose depressive symptoms have stabilized and require continuing treatment to prevent a relapse or return of symptoms.

Prozac 90 mg weekly capsules are to be taken 7 days after the last daily dose of fluoxetine 20mg. Prozac Weekly, with its long-half and enteric coating, allow 90 mg to be slowly released in the bloodstream over 7 days.

**Prozac Weekly** will be considered for coverage under the pharmacy benefit program when **all** of the following criteria are met:

1. A documented diagnosis of Major Depressive Disorder MDD.

2. The member is over the age of 18 years old.

3. A documented trial evidenced by prescription claims history of at least 30 days and failure or intolerance supported by chart notes of **all** of the following formulary alternatives at a maximum therapeutic or tolerated dose: escitalopram, citalopram, fluoxetine, fluvoxamine (including extended-release), paroxetine (including extended-release), sertraline, venlafaxine (including extended-release), duloxetine (20, 30, and 60 mg), desvenlafaxine, bupropion, and mirtazapine.
   OR
   The member is unable to physically self-administer an antidepressant medication daily for documented reasons other than non-compliance.

**Quantity limits:** #4 per 30 days.

**Approval Length:** 12 months.

**Continuation criteria:**

1. Documentation the member is receiving a positive clinical response.
References:


Criteria last updated 04/2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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</thead>
<tbody>
<tr>
<td>PULMICORT RESPULES</td>
<td>budesonide</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**PULMICORT RESPULES** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a diagnosis of asthma.

2. The member must meet one of the following age requirements:
   a. The member is 12 months to 8 years of age.
   b. The member is 9 years of age and older AND unable to use an oral aerosol inhaler.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

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**References**


Criteria last reviewed: 6/2019
Ramelteon is a melatonin agonist indicated for the treatment of insomnia characterized by difficulty with sleep onset. The clinical trials performed in support of efficacy were up to 6 months in duration.

The recommended and maximum dose per day is 8 mg taken within 30 minutes of going to bed.

Ramelteon will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has diagnosis of chronic insomnia (trouble initiating or maintaining sleep for at least three nights per week for at least three months).
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days and failure of each of the following at maximum therapeutic doses:
   a. Zolpidem up to 10 mg.
   b. Temazepam 30 mg
   OR
   Member has history of addiction to controlled substances.

Quantity limits: #30 per 30 days.

Initial/continuation Approval Length: 12 months.

Continuation criteria:

1. Documentation member is receiving a positive clinical response evidenced by a decrease in nights per week with sleep onset difficulties.

Exclusions:

1. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate).

References:

Criteria last reviewed and updated: 04/2019
Ranexa is FDA indicated for the treatment of chronic angina. It may be used with beta-blockers, nitrates, calcium channel blockers, antiplatelet therapy, lipid-lowering therapy, ACE inhibitors and angiotensin receptor blockers.

The mechanism of action of its antianginal effects has not been determined. The recommended initial dosing is 500 mg twice daily, and it may be increased to a maximum of 1000 mg twice daily, as needed, based on clinical symptoms.

Ranexa will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic symptomatic angina, and the initial prescription has been written by a cardiologist. Refills may be written by the primary care provider.

2. Within a reasonable therapeutic time period at maximally tolerated doses, the member has tried and failed a beta blocker or calcium channel blocker and a long-acting nitrate in combination.

3. The member has tried and failed generic Ranolazine ER for at least 60 days.

4. The member does not have any of the following:
   - Hepatic cirrhosis.
   - Pre-existing QT prolongation.
   - Concurrent therapy with a strong CYP3A4 inhibitor such as ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir or saquinavir.
   - Concurrent therapy with a CYP3A4 inducer such as rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine or St. John’s wort.
   - Acute renal failure, particularly in individuals with a baseline CrCL < 30 mL/min.

**Approval length**: 12 months.

**Approvable quantity**: Up to 1000 mg twice daily.

Continuation criteria (all must be met):

1. Member’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the member’s condition at that time.

2. Member has been adherent with Ranexa fills unless extenuating circumstances exist (hospitalization, medical procedures, etc.).

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>RANEXA®</td>
<td>ranolazine</td>
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### CRITERIA FOR COVERAGE/NONCOVERAGE
3. Documentation the member is tolerating the medication and there continues to be a medical need.
4. Documentation the member has responded to treatment due to a documented decrease in anginal attacks.

References:

Criteria revised 6/2019
**Ranolazine ER** is FDA indicated for the treatment of chronic angina. It may be used with beta-blockers, nitrates, calcium channel blockers, antiplatelet therapy, lipid-lowering therapy, ACE inhibitors and angiotensin receptor blockers.

The mechanism of action of its antianginal effects has not been determined. The recommended initial dosing is 500 mg twice daily, and it may be increased to a maximum of 1000 mg twice daily, as needed, based on clinical symptoms.

**Ranolazine ER** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic symptomatic angina, and the initial prescription has been written by a cardiologist. Refills may be written by the primary care provider.

2. Within a reasonable therapeutic time period at maximally tolerated doses, the member has tried and failed a beta blocker or calcium channel blocker and a long-acting nitrate in combination.

3. The member does not have any of the following:
   - Hepatic cirrhosis.
   - Pre-existing QT prolongation.
   - Concurrent therapy with a strong CYP3A4 inhibitor such as ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir or saquinavir.
   - Concurrent therapy with a CYP3A4 inducer such as rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine or St. John’s wort.
   - Acute renal failure, particularly in individuals with a baseline CrCL < 30 mL/min.

**Approval length:** 12 months.

**Approvable quantity:** Up to 1000 mg twice daily.

Continuation criteria (all must be met):

1. Member’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the member’s condition at that time.

2. Member has been adherent with Ranexa fills unless extenuating circumstances exist (hospitalization, medical procedures, etc.).

3. Documentation the member is tolerating the medication and there continues to be a medical need.
4. Documentation the member has responded to treatment due to a documented decrease in anginal attacks.

References:

Criteria revised 6/2019
**Brand Name** | **Generic Name**  
---|---  
RECTIV | nitroglycerin rectal ointment  

**CRITERIA FOR COVERAGE/NON-COVERAGE**

RECTIV (nitroglycerin rectal ointment) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Documented diagnosis of anal fissure

2. Documented history (within the past 60 days) of trial and failure of, or contraindication to ALL of the following:
   a. fiber supplements (eg Metamucil)
   b. stool softeners (eg docusate)
   c. topical medicated creams (eg Proctofoam-HC, Protocort)

3. 8 week trial and failure of, or contraindication to one of the below:
   a. compounded topical nitroglycerin + hydrocortisone
   b. compounded topical nifedipine
   c. oral nifedipine

Approval duration: 8 weeks

Continuation criteria:

1. Persistence of anal fissures

Re-approval duration: 8 weeks
**Non-Formulary PCSK 9 Agent - Brand Name (Generic)**

REPATHA (evolocumab)

**CRITERIA FOR COVERAGE/NONCOVERAGE**

REPATHA will be considered for coverage under the pharmacy benefit when the following criteria are met:

**Criteria for Initial Therapy:**

1. Must be prescribed by, or in conjunction with, a cardiologist, endocrinologist, or lipid specialist
2. Member meets either (a), (b) or (c) below including applicable criteria:
   a. Member is 18 years of age or older and has established cardiovascular disease and using to reduce the risk of myocardial infarction, stroke, or coronary revascularization.
   b. Member is 18 years of age or older and has primary hyperlipidemia (including Heterozygous Familial Hypercholesterolemia (HeFH)).
   c. Member is 13 years of age or older and has diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by ONE of the following:
      i. Genetic confirmation of 2 mutant alleles at LDL receptor (LDLR), ApoB-100, PCSK9.
      ii. Pre-treatment LDL > 500 mg/dL or treated LDL > 300 mg/dL AND xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents
3. Member has been educated to follow a lipid-lowering diet and has been counseled on healthy lifestyles to reduce cardiovascular risk including smoking and/or tobacco cessation, maintaining a healthy weight and physical activity.
4. Baseline and current LDL-C must be submitted.
5. Documentation member had inadequate response (did not achieve ≤ 50% reduction in LDL-C from baseline or LDL-C is ≥ 100 mg/dL with ASCVD or is ≥ 130 mg/dL without ASCVD) after 90-day trial of TWO high-intensity statins at maximum dosage (atorvastatin 40mg-80mg, rosuvastatin 20-40mg) in combination with ezetimibe (prior authorization required).
   Note to rph: If patient has intolerance to statin therapy another lipid therapy such as bile acid sequestrants, fibrate can be considered
6. Contraindication/intolerance to a high intensity statin defined as ONE of the following:
   a. Documentation member tried statins (pravastatin, simvastatin, atorvastatin, rosuvastatin) and had skeletal muscle related symptoms (e.g., pain, aches; weakness or muscle cramping OR abnormal biomarkers (e.g., ALT/AST of 3 x ULN, Elevation of CK of 10 x ULN, Elevation of CK of 4 x ULN with rhabdomyolysis) that started or worsened during statin treatment and resolved when statin was stopped.
   b. Member has been re-challenged at a lower dose with a different statin.
   c. Dose reduction was attempted rather than discontinuation of statin therapy altogether.
d. Member has a condition (e.g., chronic liver disease) and statin therapy is contraindicated.

7. For a diagnosis of homozygous familial hypercholesterolemia, Repatha will be used in combination with statin therapy or another lipid lowering therapy (e.g., bile acid sequestrants or fibrate) if intolerance to statin therapy.

   Note: Use in combination with other lipid lowering therapy is not required for primary hyperlipidemia (including heterozygous familial hyperlipidemia) or prevention of cardiovascular events in patients with established cardiovascular disease.

Initial approval duration: 3 months

Criteria for Continuing Therapy)

A. Lipid panel including LDL-C within past 3 months must be submitted

B. Documentation member has been compliant and had LDL-C reduction from baseline (e.g., prior to Repatha therapy) while on Repatha therapy

C. For a diagnosis of homozygous familial hypercholesterolemia, medication will continue to be used in combination with a statin or another lipid lowering therapy if intolerance to statin therapy.

Continuation approval duration: 12 months.

Quantity Limit:

1. Primary Hyperlipidemia (including Heterozygous familial hypercholesterolemia (HeFH)) and prevention of cardiovascular events: 140 mg #2/28 days OR 420mg, #1/28days.

2. Homozygous familial hypercholesterolemia (HoFH): 420mg, #1/28days

References:


<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESTASIS</td>
<td>cyclosporine</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Please note: Only Restasis SINGLE DOSE vials are formulary. Restasis Multidose is a non-formulary product.**

RESTASIS/cyclosporine will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. Member is 16 years or older
2. Member has one of following diagnoses:
   a. Sjögren's syndrome
   b. Treated for Ocular graft vs Host disease or Corneal transplant rejection
   c. Chronic dry eye syndrome
   d. Keratoconjunctivitis sicca (KCS)
   e. Keratitis sicca
   f. Xerophthalmia
3. Prescribed by an ophthalmologist, rheumatologist or optometrist
4. Member has functional lacrimal gland
5. Documentation or prescription claim history supporting trial and failure of TWO separate 30-day trials of ocular lubricating solutions or ointment.
6. Documentation of trial and failure of punctal plugs.
7. There is no presence of current ocular infection (e.g. herpes keratitis).
8. Member is not currently taking topical anti-inflammatory drugs or using punctal plugs

Initial and reauthorization duration of approval: 12 months

Continuation criteria:

1. Documentation member has been compliant and had increased tear production and improvement in dry eye disease (DED) symptoms.

References
4. Shtein, RM. Dry eyes. UpToDate. Waltham, MA.
Criteria last reviewed and updated: 04/2019
**Covered Products**

Ribavirin oral products

---

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Ribavirin** will be considered for coverage under the pharmacy benefit program when the following criteria are met: The member has one of the following diagnoses:

1. **Chronic HCV** – In combination with other hepatitis C virus antiviral drugs for the treatment of chronic HCV in patients 18 years and older with compensated liver disease

AND

2. Female: Patient is not pregnant and willing to use contraceptive prevention methods.

AND


AND

4. Ribavirin is distributed/dispensed by a designated Specialty Pharmacy.

AND

Approval duration will vary dependent upon patient’s genotype and treatment history.

This guideline will be reviewed on an annual basis.

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References

Criteria last updated 09/2016; Last reviewed April 2019
Brand name RINVOQ (upadacitinib) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Documented diagnosis of rheumatoid arthritis
2. Prescribed by or in consultation with a rheumatologist
3. Age ≥ 18 years
4. Documentation submitted member has no latent or active tuberculosis infection
5. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) and one or more of the following:
   a. Clinical Disease Activity Index (CDAI) > 10.0
   b. Disease Activity Score 28 (DAS) ≥ 3.2
   c. Simplified Disease Activity Index (SDAI) > 11.0
6. Trial and failure of one of the following therapies unless intolerant or contraindicated:
   a. Methotrexate for ≥ 3 consecutive months
   b. If documented intolerance or known contraindication to methotrexate, then one of the following disease-modifying antirheumatic agent for ≥ 3 consecutive months:
      • Hydroxychloroquine
      • Sulfasalazine
      • Leflunomide
7. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
8. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

Maximum quantity: one 15mg tablet once daily

Approval duration: Three months

**Continuation Criteria:**

1. Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters by supporting a result of at least one of the following disease activity measurements listed below.
   • Clinical Disease Activity Index (CDAI) < 10.0
• Disease Activity Score 28 (DAS) ≤ 3.2
• Simplified Disease Activity Index (SDAI) < 11.0

Re-approval duration: up to 12 months thereafter based on clinical response

Exclusions:

1. Needle phobia is not considered a clinical reason for the use of Rinvoq instead of the required alternatives unless it meets DSM-V-TR 300.29 (Specific Phobia).
2. Concomitant use with other biologic DMARD medications (oral and injectable).
3. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
4. The following is a list of acceptable contraindications for the use of methotrexate:
   • Pregnancy
   • Actively breast-feeding
   • Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   • Immunodeficiency syndrome
   • Hepatitis B or C infection
   • Liver enzymes that are persistently elevated
   • Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider
<table>
<thead>
<tr>
<th>Covered products</th>
<th>Brand or generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rivastigmine oral capsule</td>
<td>EXELON</td>
</tr>
<tr>
<td>Rivastigmine oral solution</td>
<td>EXELON</td>
</tr>
<tr>
<td>Rivastigmine patch</td>
<td>EXELON</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

*Rivastigmine* is an acetylcholinesterase inhibitor indicated for treatment of mild, moderate, and severe dementia of the Alzheimer’s type and mild to moderate dementia associated with Parkinson’s disease.

The recommended dosage of rivastigmine capsules and oral solution in Alzheimer’s disease is 6 mg to 12 mg per day, taken twice a day. There is evidence from the clinical trials that doses at the higher end of this range may be more beneficial.

The recommended dosage of rivastigmine capsules and oral solution shown to be effective for dementia associated with Parkinson’s disease is 3 mg to 12 mg per day, taken twice a day.

The recommended dosage of rivastigmine patches is as follows:

- **Mild to Moderate Alzheimer’s Disease and Parkinson’s Disease Dementia:** 9.5 mg/24 hours or 13.3 mg/24 hours once daily.
- **Severe Alzheimer’s Disease:** 13.3 mg/24 hours once daily.

*Rivastigmine* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member must be 18 years old or older.
2. The initial prescription has been written by a psychiatrist, neurologist, or physician who specializes in the care of the elderly such as a geriatrician. Refills may be written by the primary care provider.
3. Documented diagnosis of mild to moderate dementia associated with Alzheimer’s disease or Parkinson’s disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of one of the below:
   a. Between 20 - 24 for mild disease.
   b. Between 13- 20 points for moderate disease.

**OR**

4. Documented diagnosis of severe dementia associated with Alzheimer’s disease defined by a baseline (within 90 days) Mini Mental State Examination [MMSE] score of the below.
a. Less than 13 points for severe disease.

OR

5. Documented diagnosis of multi-infarct (vascular) dementia and brain imaging confirms evidence of cerebrovascular disease (CVD). Cognitive screening test results such as MMSE, mini-cog, 7 minute screen, Montreal Cognitive Assessment (MOCA) or SLUMS must be included.

Quantity Limits:

- Rivastigmine capsules – Up to #60 per 30 days.
- Rivastigmine solution – Up to 180 mL per 30 days.
- Rivastigmine patches – #30 per 30 days

Length of Approval: Three months initially to establish a symptomatic clinical response is occurring with no intolerable side effects. Approval for 12 months thereafter.

Continuation Criteria:

1. Documentation member is receiving a positive clinical response evidenced by a decrease in MMSE score for dementia related to Alzheimer’s Disease or Parkinson’s Disease.
2. Documentation member is receiving a positive clinical response evidenced by an improvement in cognitive testing for vascular dementia.

Exclusions:

1. Not for use for non-AD dementias, such as dementia with Lewy bodies (DLB) and frontotemporal dementia due to a lack of evidence and guideline support.

References:

Criteria updated 4/2019
**Nonformulary**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROZEREM</td>
<td>Ramelteon</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

*Rozerem* is a melatonin agonist indicated for the treatment of insomnia characterized by difficulty with sleep onset. The clinical trials performed in support of efficacy were up to 6 months in duration.

The recommended and maximum dose per day is 8 mg taken within 30 minutes of going to bed.

*Rozerem* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has diagnosis of chronic insomnia (trouble initiating or maintaining sleep for at least three nights per week for at least three months).
2. The member is over the age of 18 years old.
3. The member has a documented trial/failure of at least 60 days of generic Ramelteon
4. A documented trial of at least 30 days and failure of each of the following at maximum therapeutic doses:
   a. Zolpidem up to 10 mg.
   b. Temazepam 30 mg
   OR
   Member has history of addiction to controlled substances.

**Quantity limits:** #30 per 30 days.

**Initial/continuation Approval Length:** 12 months.

**Continuation criteria:**

1. Documentation member is receiving a positive clinical response evidenced by a decrease in nights per week with sleep onset difficulties.

**Exclusions:**

1. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate).

**References:**
   Criteria last reviewed and updated: 04/2019
Short acting opioid therapy exceeding a 5 day supply will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

A. If the member meets one of the following conditions as outlined in AHCCCS AMPM Policy 310-V, Exhibit 310-V-2, the request may be approved for the appropriate duration of therapy with a maximum duration of 6 months:
   1. The member has a diagnosis of neoplasm related pain (ICD-10 code G89.3).
   2. The member is enrolled in Hospice Care.
   3. The use of the short-acting opioid is for “end-of-life care” (other than hospice).
   4. The use of the short-acting opioid is for palliative care.
   5. The use of the short-acting opioid is for a child on opioid wean at the time of hospital discharge.
   6. The use of the short-acting opioid is for a traumatic injury, excluding post-surgical procedures, as outlined in AHCCCS AMPM Policy 310-V, Exhibit 310-V-3.
   7. The use of the short-acting opioid is for a post-surgical procedure. Up to 14 day supply is approvable per AHCCCS AMPM policy 310-V, however greater than 14 day supply requires clinical review.

B. For other conditions of acute or chronic pain not mentioned above, the following information and documentation is required:
   1. Documented comprehensive medical and pain related evaluation
   2. The member has a documented trial and failure of non-pharmacologic treatment
   3. The member has a documented trial and failure of non-opioid medications (e.g. topical NSAIDs, analgesics or anesthetics, and oral NSAIDs and muscle relaxants)
   4. The prescriber has included the estimated duration of therapy and the treatment plan
   5. The prescriber has educated the member on the potential side effects of using narcotic analgesics, including the risk for misuse, abuse and addiction related to continuing on opioid therapy
   6. The member has been assessed for behaviors indicative of a developing substance abuse disorder including but not limited to abuse/misuse of current prescriptions
   7. The prescriber has reviewed the member’s profile in the AZ CSPMP (Controlled Substances Prescription Monitoring Program) within the last 30 days from the date of the request
      a. Oncologists who are prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to review the member’s CSPMP profile
   8. UDS may be required by clinical reviewer on case specific basis

C. The prescriber must provide chart notes or other evidence that coordination of care is present IF:
   1. The prescriber is not the primary care physician (need evidence of coordination of care
w/ PCP)
2. The patient is being treated by a behavioral health provider and prescriber is not the BH provider (need evidence of coordination of care w/ BH provider)
   (If the patient is in a substance abuse treatment program, there must be a patient signed medical release to share information between providers)

**Duration of approval:** Duration requested by provider with a maximum of 6 months.

References:

1. AHCCCS AMPM Chapter 300, Policy 310-V and Chapter 900, Policy 960.

Criteria updated 03/2017; Last reviewed 3/2019
### Criteria Name

Non Formulary and Quantity Limit Short Acting Opioids

### CRITERIA FOR COVERAGE/NONCOVERAGE

**Non Formulary and Quantity limit Short Acting Opioids** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

**Required information and documentation for all non-formulary short acting opioids (Schedule C2 and C3) must be submitted by the prescriber with the authorization request:**

1. Documented comprehensive medical and pain related evaluation that includes the member’s medication history, trial and failures of non-opioid medications
2. Specialist assessment of pain related diagnosis (orthopedics, neurologist, rheumatologist, gastroenterologist, oncologist and pain management specialist). If specialist is unavailable, requests from primary care provider are acceptable.
3. The prescriber has educated the member on the potential side effects and risks of using narcotic analgesics.
4. The member does not display behaviors of developing and opioid use disorder.
5. The prescriber has reviewed the member’s profile in the AZ CSPMP (Controlled Substances Prescription Monitoring Program) within the last 30 days from the date of the request.
   
   **Note:** Oncologists prescribing opioids to treat pain secondary to an active cancer diagnosis are not required to review the member’s CSPMP profile.

6. Documentation of a random drug screen collected within the past 4 months from the date of the request.
   
   **Note:** Members being treated for pain secondary to an active cancer diagnosis or who are in hospice are or at end of life are not required to submit a UDS.

7. The prescriber must provide chart notes or other evidence that coordination of care is present if:
   a. The prescriber is not the primary care physician
   b. The patient is being treated by a behavioral health provider and prescriber is not the BH provider
   c. If the patient is in a substance abuse treatment program, there must be a patient signed medical release to share information between providers

**Coverage Guidelines for medical necessity (formulary exception):**

- Member indication/diagnosis consistent with FDA approved uses and no contraindications to use are present
- Documented member trial and failure and/or contraindications of at least THREE formulary products.
- Certain opioids will require the member to be considered as opioid tolerant (members who have been taking, for 1 week or longer, morphine 60 mg/day or more, fentanyl transdermal
25 mcg/h or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, oral oxymorphone 25 mg/day or more, or an equianalgesic dose of another opioid.

*Note: If member is new to drug therapy, the need for greater than an initial 5 day supply will be need to be addressed (Refer to criteria for “Short Acting Opioid Therapy Exceeding a 5 Day Supply”)*

**Coverage Guidelines for exceeding established Quantity Limit (formulary) – must meet (1), (2) and (3):**

1. The maximal doses specified under the quantity restriction has been tried for an adequate period of time and been deemed ineffective in the treatment of the member’s disease or medical condition.
   
   a. If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition.

2. There is documented clinical rationale for the requested dosage, quantity, or duration of medication.

3. The requested dosage, quantity, or duration is safe and effective based on clinical evidence or medical and scientific evidence contained in peer-reviewed medical literature, accepted Standards of medical practice, and/or one of the following Compendia:
   
   a. American Hospital Formulary Service (AHFS) Compendium
   b. Micromedex/DrugDex (not Drug Points) Compendium
   c. Elsevier Gold Standard's Clinical Pharmacology Compendium
   d. National Comprehensive Cancer Network Drugs and Biologics Compendium

**Approval Time Period: 6 months**

*Note: For patients under the age of 18, prescriptions for all opioid medications (long and short acting) will be limited to a 5 day supply except in the case of cancer, other chronic disease, or traumatic injury which will be reviewed on a case-by-case basis.*

a. For diagnosis of cancer or other chronic disease, approval duration will be for six months.

b. For traumatic injury, approval duration will be for the requested duration or up to a maximum of three months.

c. Refer to criteria “Short Acting Opioid Therapy Exceeding a 5 Day Supply”

**References**


Criteria updated 7/2019
SELZENTRY / Maraviroc will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. The member must be clinically diagnosed with CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay
2. Member is 2 years of age or older
3. Member is currently taking or will be prescribed an optimized background antiretroviral therapy regimen
4. Medication must be prescribed by, or in conjunction with, an HIV specialist

Duration of approval: 12 months.

Authorization for continued use shall be reviewed after 12 months to confirm there is documentation of positive clinical response to Selzentry therapy.

References:
Criteria last updated: June 2019
**CRITERIA FOR COVERAGE/NONCOVERAGE**

**SENSIPAR** will be considered for coverage when the following criteria are met:

1. Member must be clinically diagnosed with one of the following conditions and meet individual criteria if stated:
   
   **A. Secondary hyperparathyroidism due to chronic kidney disease** who meet (a) and (b) below:
      
      a. Member is on dialysis
      b. Documented trial and failure, intolerance, or contraindication to both of the following:
         
         i. A phosphate binder (e.g. calcium acetate, Fosrenol/Lanthanum, Renvela, Renagel)
         ii. A vitamin D analog (e.g. calcitriol, doxercalciferol, Zemplar)
   
   **B. Hypercalcemia due to parathyroid carcinoma**

   **C. Severe hypercalcemia (calcium > 12.5mg/dL) with primary hyperparathyroidism and unable to undergo parathyroidectomy**

2. iPTH is $\geq 300$ pg/mL (biPTH $> 160$) and calcium is $\geq 8.4$ mg/dL in order to initiate therapy

3. Patient has a documented trial/failure of at least 60 days of generic Cinacalcet

**Approval length:** Three months initially. If member meets guidelines for continuation, approval can be extended to 12 months.

**Continuation Criteria:**

1. The member has experienced a reduction in serum calcium from baseline
2. The member does not have hypocalcemia

**References**


Criteria last reviewed: 6/2019
SEREVENT DISKUS will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member must be clinically diagnosed with one of the following disease states and meet their individual criteria:

1. Asthma
   a. Member must be 4 years of age and older
   b. Must be used in combination with an inhaled corticosteroid

2. Chronic obstructive pulmonary disease
   a. Member must be 18 years of age and older

3. Exercise-induced asthma; prophylaxis
   a. Member must be 4 years of age and older

4. Nocturnal asthma
   a. Member must be 4 years of age and older
   b. Must be used in combination with an inhaled corticosteroid

Exclusions from coverage include:

- The use of Serevent/salmeterol as monotherapy for the treatment of asthma or nocturnal asthma.
- The use of Serevent/salmeterol when dosed more than twice a day (12 hours apart).

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References


Criteria last reviewed: 6/2019
CRITERIA FOR COVERAGE/NONCOVERAGE

Jardiance, Invokana or Farxiga will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member must meet the following criteria for initial authorization:

1. Baseline A1c or goals of therapy
2. The member has diagnosis of Type 2 Diabetes Mellitus (DMII) and established atherosclerotic cardiovascular disease (ASCVD), heart failure (HF) or chronic kidney disease (CKD)
   - Failure to obtain adequate glycemic control (A1c) after at least a 2 months (60 days) trial of maximum tolerated dose of metformin
     OR
   - Member is unable to take metformin due to intolerance (defined as ongoing GI problems (diarrhea, nausea, abdominal cramping) OR has contraindication (e.g., eGFR below 30mL/min).
     • eGFR ≥ 30-59 ml/min.

3. The member has a diagnosis of Type 2 Diabetes Mellitus (DMII) and no cardiovascular disease
   - Failure to obtain adequate glycemic control (A1c) after at least a 2 months (60 days) trial of metformin and ONE additional diabetic agent (e.g., sulfonylureas (SU), dipeptidyl peptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 (GLP-1) agonists, insulin, pioglitazone) OR metformin in combination of Insulin; OR another diabetic regimen if member is unable to take metformin due to intolerance (defined as ongoing GI problems (diarrhea, nausea, abdominal cramping) OR has contraindication (e.g., eGFR below 30mL/min).
     • eGFR ≥ 45mL/min.

Initial approval duration: 6 months

Continuation Criteria:

1. Member had improvement in target goals (a reduction in hemoglobin A1C, glucose level) since starting this therapy (3-6 months) does not have adverse effects or contraindications.
Continuation approval duration: 12 months

Exclusion:

- Pre-diabetic patients (e.g., HbA1c ≥ 5.7% and FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L) OR HbA1c <5.7%).

References:


Criteria last reviewed/updated: September 2019
<table>
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<th>Brand Name</th>
<th>Generic Name</th>
</tr>
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<tbody>
<tr>
<td>SIGNIFOR</td>
<td>pasireotide</td>
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**CRITERIA FOR COVERAGE/NONCOVERAGE**

**SIGNIFOR® (pasireotide)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

**Initial coverage:**

1. Patient has a diagnosis of (pituitary) Cushing’s disease and is 18 years of age or older
2. Prescribed by endocrinologist
3. Pituitary surgery is not an option or has not been curative
4. Baseline hepatic function lab work dated within the past 30 days has been provided

**Continuation Criteria:**

1. Documentation that the patient has experienced an objective response to therapy (i.e., clinically meaningful reduction in 24-hour urinary free cortisol levels and/or improvement in signs or symptoms of the disease).

**Approval Length:** Three months initially then up to 12 months thereafter

**Quantity Limits:** SIGNIFOR (pasireotide) is subject to a quantity limit of 2 units/day.

**References**


Criteria last reviewed and updated: 4/2019
Silenor is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance. The clinical trials performed in support of efficacy were up to three months in duration.

The recommended and maximum dose of Silenor for adults is 6 mg once daily. A 3 mg once daily dose may be appropriate for some patients, if clinically indicated.

Silenor will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia (trouble initiating or maintaining sleep for at least three nights per week for at least three months).
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days and failure of each of the following at the maximum therapeutic doses:
   a. Zolpidem 10 mg.
   b. Temazepam 30 mg.
   OR
   Member has history of addiction to controlled substances.

Quantity limits: #30 per 30 days.

Initial/continuation Approval Length: 12 months.

Continuation criteria:

1. Documentation member has been reevaluated for continued necessity and is receiving a positive clinical response evidenced by a decrease in nights per week with sleep maintenance difficulties.

Exclusions:

1. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate).
References:
Siliq is a self-administered subcutaneous injection of human interleukin-17 receptor A (IL-17RA) antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

Siliq will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Plaque Psoriasis (Adult)**
   a. Prescribed by or in consultation with a dermatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of **moderate to severe** plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
      
      **Note:** An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.
   e. Documentation member has failed topical therapy for a trial of at least 90 days and includes **two** of the following verified by prescription claims history:
      i. Calcipotriene (generic for Dovonex) topical preparations
      ii. Medium-to-high potency corticosteroids
         
         **Note:** For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
      iii. Tazorac topical gel 0.05%
      iv. Tacrolimus 0.1% (prior authorization required) ointment
      v. Coal tar preparations such as coal tar shampoo
   f. Member has failed **one** of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
      ix. Methotrexate oral tablets
      x. Cyclosporine oral capsules
   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both **Humira** (adalimumab) and **Enbrel** (etanercept).
   h. Documentation submitted supporting Siliq will be self-administered by the member at a maintenance dosing interval of no less than every 2 weeks after the initial dosing of one injection at Week 0, Week 1, and Week 2.
Approval Length: Six months initially then up to 12 months thereafter based on clinical response.

Quantity Limits:

*Induction dosing* – Three prefilled syringes per 30 days for a one time approval.

*Maintenance dosing* – Two prefilled syringes per 30 days.

Continuation Criteria:

*Psoriasis* – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters based on decreased total percent BSA affected.

Exclusions:

1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
2. Concomitant use with other biologic medications (oral and injectable).
3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:


Criteria updated: 5/2019
Simponi is a tumor necrosis factor (TNF) blocker available as a self-administered subcutaneous injection indicated for the treatment of adult patients with:

- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Active ankylosing spondylitis (AS)
- Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy
  - inducing and maintaining clinical response
  - improving endoscopic appearance of the mucosa during induction
  - inducing clinical remission
  - achieving and sustaining clinical remission in induction responders

Simponi will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or provider attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Hydroxychloroquine
      iii. Leflunomide
      iv. Sulfasalazine
   f. Prescribed concomitantly with MTX or another agent if intolerance or contraindication to MTX;
      
      *Note: Per 2015 ACR (American College of Rheumatology) Treatment Guidelines for Rheumatoid Arthritis, biologic therapy should be used in combination with methotrexate, when possible, due to superior efficacy of this combination over biologic monotherapy.*

   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
h. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of, at least three of the following:
   - Olumiant (baricitinib)
   - Kevzara (sarilumab)
   - Actemra (tocilizumab)
   - Cimzia (certolizumab)

i. Documentation submitted supporting Simponi will be self-administered by the member at a maintenance dose of 50 mg and at a dosing interval of no less than every 4 weeks.

2. Psoriatic arthritis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe psoriatic arthritis per chart notes or prescriber attestation
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Leflunomide
      iii. Sulfasalazine
   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
   h. Documentation submitted supporting Simponi will be self-administered by the member at a maintenance dose of 50 mg and dosing interval of no less than every 4 weeks.

3. Ankylosing Spondylitis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Documentation submitted member has no latent or active tuberculosis infection.
   c. Age ≥ 18 years old.
   d. Documented diagnosis of ankylosing spondylitis.
   e. Trial and failure, unless intolerant or contraindication, per documentation submitted and per prescription claims history of the following:
      i. Two or more prescription required non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, and for greater than 30 days.

   Formulary NSAIDs include: ibuprofen, naproxen, naproxen DR, piroxicam, diclofenac, meloxicam, nabumetone, oxaprozin, indomethacin, indomethacin ER, flurbiprofen, fenoprofen, and etodolac.
Note: Oral NSAIDs are recommended as the first-line drug for ankylosing spondylitis per the 2016 ASAS/EULAR guidelines

f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
g. Documentation submitted supporting Simponi will be self-administered by the member at a maintenance dose of 50 mg and dosing interval of no less than every 4 weeks.

4. Ulcerative colitis
   a. Prescribed by or in consultation with a gastroenterologist.
   b. Age ≥ 18 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of moderately to severely active ulcerative colitis.
   e. Member has failed two of the following therapies verified per prescription claims history for ≥ 3 consecutive months, unless supported intolerance or contraindication submitted.
      i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
      ii. An oral corticosteroid or controlled ileal release budesonide
      iii. A thiopurine such as azathioprine
      iv. Methotrexate up to 25 mg once weekly
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of Humira (adalimumab).
   g. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of Xeljanz (tofacitinib).
   h. Documentation submitted supporting Simponi will be self-administered by the member at a maintenance dose of 100 mg and dosing interval of no less than every 4 weeks after the initial induction dosing of 200 mg at Week 0, 100 mg at Week 2.

Approval Length: Six months initially then up to 12 months thereafter based on clinical response.
Quantity Limits:  
Rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis – One 50 mg prefilled syringe per 30 days.  
Ulcerative colitis – One 100 mg prefilled syringe per 30 days every 4 weeks after initial induction dosing of up to three 100 mg syringes for the first month.

Continuation Criteria:  
Rheumatoid arthritis and psoriatic arthritis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.  
Ankylosing spondylitis – Documentation submitted supporting decrease in at least one of the following  
5. Back pain  
6. Serum C-reactive protein  
Ulcerative colitis – One of the following must be met:  
1. Documentation submitted supporting symptomatic remission has occurred OR a total Mayo Disease Activity Index score of 0-2.
2. Documentation submitted supporting decrease in overall symptoms from pre-treatment baseline of all, or a majority of symptoms (weight loss, abdominal pain or tenderness, intermittent nausea or vomiting, or significant anemia).

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

**Exclusions:**
1. Concomitant use with other biologic DMARD medications (oral and injectable).
2. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
3. The following is a list of acceptable contraindications for the use of methotrexate:
   
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**References:**

Criteria updated: 5/2019
Sivextro (tedizolid phosphate) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has been clinically diagnosed with Acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of gram-positive microorganisms (namely, Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin- susceptible [MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis.)

2. Culture and sensitivity indicates susceptibility to tedizolid (SIVEXTRO)

3. Member must have tried/failed/contraindication to preferred prior authorized alternative: linezolid

4. Member not taking Zyvox (linezolid) concurrently.

5. Quantity Limit: 200mg once daily: 6 tablets /30 days; one dose per day for six days.

Authorization will be for duration of therapy not to exceed 6 days of therapy (including doses given in hospital, emergency room, or urgent care). Additional course of therapy will require new PA submission and clinical notes documenting response and need for additional therapy.

This guideline will be reviewed on an annual basis.

References:

Criteria last reviewed: 6/2019
Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of adults with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis (PsA), alone or in combination with methotrexate.
- Moderately to severely active Crohn’s disease (CD) who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers.

Adolescent patients (12 years or older) with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.

Stelara will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Plaque Psoriasis (Adult)**
   a. Prescribed by or in consultation with a dermatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
      
      **Note:** An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.
   e. Documentation member has failed topical therapy for a trial of at least 90 days and includes two of the following verified by prescription claims history:
i. Calcipotriene (generic for Dovonex) topical preparations
ii. Medium-to-high potency corticosteroids
   
   **Note:** For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
iii. Tazorac topical gel 0.05%
iv. Tacrolimus 0.1% (prior authorization required) ointment
v. Coal tar preparations such as coal tar shampoo

f. Member has failed **one** of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
   i. Methotrexate oral tablets
   ii. Cyclosporine oral capsules

   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both **Humira** (adalimumab) and **Enbrel** (etanercept).

   h. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of at least **three** of the following:
      - Cimzia (certolizumab)
      - Cosentyx (secukinumab)
      - Otezla (apremilast)
      - Siliq (brodalumab)
      - Infliximab (biosimilar to Remicade)

j. Current weight is documented and dated within the past 90 days and resulting dose calculated is consistent with the FDA labeled dosing.

k. Documentation submitted supporting Stelara will be self-administered by the member at a maintenance dosing interval of no less than every 12 weeks after the initial dosing of one injection at Week 0 and at Week 4.

2. **Plaque Psoriasis (adolescents age 12 to 17 years old)**
   a. Prescribed by or in consultation with a dermatologist.
   b. Age ≥ 12 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of **moderate to severe** plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
      
      **Note:** An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.

   e. Documentation member has failed topical therapy for a trial of at least 90 days and includes **two** of the following verified by prescription claims history:
i. Calcipotriene (generic for Dovonex) topical preparations
ii. Medium-to-high potency corticosteroids
   
   **Note:** For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.

iii. Tazorac topical gel 0.05%
iv. Tacrolimus (prior authorization required) ointment
v. Coal tar preparations such as coal tar shampoo

f. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
   i. Methotrexate oral tablets
   ii. Cyclosporine oral capsules


g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of Enbrel (etanercept).

h. Current weight is documented and dated within the past 90 days and resulting dose calculated is consistent with the FDA labeled dosing.

j. Documentation submitted supporting Stelara will be self-administered by the member at a maintenance dosing interval of no less than every 12 weeks after the initial dosing of one injection at Week 0 and at Week 4.

3. **Psoriatic arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe psoriatic arthritis per chart notes or prescriber attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Leflunomide
      iii. Sulfasalazine

f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).

g. Member has documented trial and failure per prescription or medical claim history and chart notes, or documented contraindication to, or intolerance of five of the following:
   - Cosentyx (secukinumab)
   - Orencia (abatacept)
   - Otezla (apremilast)
   - Simponi (golimumab)
   - Xeljanz (tofacitinib)
   - Cimzia (certolizumab)
   - Infliximab (biosimilar to Remicade)

h. Current weight is documented and dated within the past 90 days and resulting dose calculated is consistent with the FDA labeled dosing.
i. Documentation submitted supporting Stelara will be self-administered by the member at a maintenance dosing interval of no less than every 12 weeks after the initial dosing of one injection at Week 0 and at Week 4.

j. Requested dose is for 45 mg unless documented co-existent moderate-to-severe plaque psoriasis exists and member also weighs more than 100 kg, and if both are present then a dose of 90 mg is indicated instead.

4. **Crohn’s Disease**
   a. Prescribed by or in consultation with a gastroenterologist.
   b. Age ≥ 18 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderately to severely active Crohn’s disease.
   e. Member has failed two of the following therapies verified per prescription claims history, unless supported intolerance or contraindication submitted, for ≥ 3 consecutive months:
      i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
      ii. An oral corticosteroid or controlled ileal release budesonide
      iii. A thiopurine such as azathioprine
      iv. Methotrexate
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of Humira (adalimumab).
   g. Member has documented trial and failure per prescription or medical claim history and chart notes or documented contraindication to, or intolerance of Cimzia (certolizumab) or infliximab (biosimilar to Remicade).
   h. Initial intravenous dose of Stelara confirmed as approved through the medical benefit and administered per medical claims.
   i. Documentation submitted supporting Stelara will be self-administered by the member at a maintenance dosing interval of no less than every 8 weeks after the initial intravenous dose.

**Approval Length for all indications:** Six months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits:**

*Plaque psoriasis* –

- **Initial dosing the first month:** One 45 mg or 90 mg prefilled syringe at Week 0 and Week 4.
- **Maintenance dosing:** One 45 mg or 90 mg prefilled syringe every 12 weeks.

*Psoriatic arthritis* –

- **Initial dosing the first month:** One 45 mg or 90 mg prefilled syringe at Week 0 and Week 4.
- **Maintenance dosing:** One 45 mg or 90 mg prefilled syringe every 12 weeks.

*Crohn’s disease* –

- **Maintenance dosing only:** One 90 mg prefilled syringe every 8 weeks.

**Continuation Criteria:**
Psoriatic arthritis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.

Psoriasis (adult and adolescent) – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters based on decreased total percent BSA affected.

Crohn’s disease – One of the following must be met unless member received initial dose by intravenous infusion then all initial pharmacy benefit criteria must be met in full.

1. Documentation submitted supporting symptomatic remission has occurred OR Crohn’s disease activity score (CDAI) < 150.
2. Documentation submitted supporting decrease in overall symptoms from pre-treatment baseline of all or a majority of symptoms (weight loss, abdominal pain or tenderness, intermittent nausea or vomiting, or significant anemia) OR a CDAI score < 220.

Exclusions:
1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
2. Concomitant use with other biologic medications (oral and injectable).
3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:

Criteria updated: 5/2019
## STEP THERAPY COVERAGE POLICY

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Targeted Drugs</th>
<th>Requirement</th>
</tr>
</thead>
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<tr>
<td>BRONCHODILATOR AGENTS</td>
<td>ADVAIR HFA, DULERA, AND SYMBICORT</td>
<td>Trial of one steroid inhaler: budesonide (Pulmicort) Flexhaler, Pulmicort Respules, Flovent HFA, Asmanex, Qvar Redihaler, or Alvesco</td>
</tr>
<tr>
<td>URINARY ANTISPASMODICS</td>
<td>TOLTERODINE IR and ER</td>
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<tr>
<td>URINARY ANTISPASMODICS</td>
<td>MYRBETRIQ</td>
<td>Trial of all generic urinary antispasmodics (i.e. oxybutynin, tolterodine, trospium chloride)</td>
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<tr>
<td>Sleep Disorder Agents</td>
<td>RAMELTEON (generic Rozerem)</td>
<td>Trial of temazepam and zolpidem</td>
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</table>

**Updated October 2019**
**SUCRAID**

**Brand Name** | **Generic Name**
---|---
SUCRAID | sacrosidase

### CRITERIA FOR COVERAGE/NON-COVERAGE

*Sucraid* is an oral solution indicated for use as an enzyme replacement therapy for the treatment of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

Sucraid will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by a gastroenterologist, endocrinologist, or genetic specialist.
2. Documentation submitted confirming a requested diagnosis of congenital sucrase-isomaltase deficiency by one of the following:
   a. Duodenal biopsy that displays, per a disaccharidase assay, low sucrase activity of less than 25 µmol/min/g and normal amounts of other disaccharides.
   b. All of the following must be met and supported by documentation:
      - Fecal pH less than 6.0
      - Breath hydrogen increase greater than 10 ppm following fasting sucrose challenge
      - Negative lactose breath test
   c. A positive genetic test for a pathogenetic mutation in the sucrase-isomaltose (SI) gene located on chromosome 3 (3q25-q26).
3. Documentation submitted supporting Sucraid therapy will be used in conjunction with dietary limitation of sucrose intake [i.e., used for meals or snacks when avoidance of sucrose is not possible or recommended]

**Approval Length:** Three months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits:** Approvable quantity based on recommended dosing per the Sucraid FDA prescribing label.

a. >15 kg (33 lbs.): 2 mL with each sucrose-containing meal or snack, but not to exceed 8 mL (4 doses) per day [one box with two 118 mL (4 oz) bottles equals a 29-day supply]

b. ≤15 kg (33 lbs.): 1 mL with each sucrose-containing meal or snack, but not to exceed 8 mL per day [one box with two 118 mL (4 oz) bottles equals a 29-day supply]

**Continuation Criteria:**

1. Documentation submitted supports a response to Sucraid treatment and must include at least three of the following:
   - Weight gain
   - Decreased diarrhea
   - Increased caloric intake
- Decreased gassiness
- Abdominal pain

2. Documentation submitted supporting dietary compliance with low-sucrose or sucrose-free diet and/or a low-starch or starch-free diet.

Exclusions:
1. Secondary or acquired sucrase-isomaltase deficiencies due to such conditions, but not all inclusive of, Celiac disease, Sprue, chemotherapy induced, Crohn’s disease, allergic enteropathy, immunodeficiency, gastroenteritis, giardiasis, small intestinal bacterial overgrowth (SIBO), Ulcerative Colitis, rapid gastric emptying, or dumping syndrome.

References:
1. Sucraid prescribing information. Vero Beach, FL. QOL Medical LLC.

Criteria reviewed: 5/2019
 Tacrolimus Ointment will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Member has diagnosis of:

1. Atopic Dermatitis (eczema)
2. Lichen sclerosus
3. Psoriasis
4. Vitiligo (on head and neck)

AND

Member has tried and failed an adequate course of therapy with TWO formulary medium to high potency topical corticosteroids OR
Member has contraindication to medium to high potency topical corticosteroids (e.g., areas involving eyelids, face, or genital areas)

AND

5. Patient is at least 15 years of age for the 0.1% dosage

AND

6. Patient is at least 2 years of age for the 0.03% dosage

Formulary covers 30gm/30days. Documentation supporting necessity of additional quantity.

Initial approval duration: 12 months.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

Very High Potency:

augmented betamethasone 0.05% (Diprolene) ointment, gel, lotion
clobetasol propionate 0.05% (Temovate) cream, ointment

<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Reference Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tacrolimus Ointment (0.03% &amp; 0.1%)</td>
<td>PROTOPIC</td>
</tr>
</tbody>
</table>
halobetasol propionate 0.05% (Ultravate) cream, ointment

**High Potency:**
augmented betamethasone 0.05% (Diprolene) cream
diflorasone 0.05% (Psorcone E, Florone) cream, ointment
fluocinonide acetonide 0.05% (Lidex) cream, ointment, gel, solution
triamcinolone acetonide 0.5% (Aristocort, Kenalog) cream, ointment

**Medium Potency:**
desoximetasone 0.05% (Topicort) cream, ointment, gel
fluocinolone acetonide 0.025% (Synalar) cream, ointment
mometasone 0.1% (Elocon) cream, ointment, lotion
triamcinolone acetonide 0.025%, 0.1% (Aristocort, Kenalog) cream, ointment

**Low Potency:**
aclometasone 0.05% (Aclovate) cream, ointment
desonide 0.05% (Desowen) cream, ointment, lotion
fluocinolone acetonide 0.01% (Synalar) solution
hydrocortisone 2.5% (Hytone) cream, ointment

References:

Criteria last reviewed and updated: 02/2019
Taltz is a humanized interleukin-17A antagonist indicated for the treatment of adults with:
- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Active psoriatic arthritis

TALTZ will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Plaque Psoriasis (Adult)
   a. Prescribed by or in consultation with a dermatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe plaque psoriasis with ≥ 10% of body surface area (BSA) affected.
      Note: An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.
   e. Documentation member has failed topical therapy for a trial of at least 90 days and includes two of the following verified by prescription claims history:
      i. Calcipotriene (generic for Dovonex) topical preparations
      ii. Medium-to-high potency corticosteroids
         Note: For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.
      iii. Tazorac topical gel 0.05%
      iv. Tacrolimus 0.1% (prior authorization required) ointment
      v. Coal tar preparations such as coal tar shampoo
   f. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
      i. Methotrexate oral tablets
      ii. Cyclosporine oral capsules
   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
h. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of at least three of the following:
   - Cimzia (certolizumab)
   - Cosentyx (secukinumab)
   - Otezla (apremilast)
   - Siliq (brodalumab)
   - Infliximab (biosimilar to Remicade)

i. Documentation submitted supporting Taltz will be self-administered by the member at a maintenance dose of 80 mg and a dosing interval of no less than every 4 weeks after the initial induction dosing of two 80 mg injections at Week 0 followed by 80mg at Weeks 2, 4, 6, 8, 10, and 12.

2. Psoriatic arthritis
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe psoriatic arthritis per chart notes or prescriber attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Leflunomide
      iii. Sulfasalazine
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
   g. Member has documented trial and failure per prescription or medical claim history and chart notes, or documented contraindication to, or intolerance, of five of the following:
      - Cosentyx (secukinumab)
      - Orencia (abatacept)
      - Otezla (apremilast)
      - Simponi (golimumab)
      - Xeljanz (tofacitinib)
      - Cimzia (certolizumab)
      - Infliximab (biosimilar to Remicade)

   i. Documentation submitted supporting Taltz will be self-administered by the member at a maintenance of 80 mg and at a dosing interval of no less than every 4 weeks after the initial dosing of two 80 mg injections at Week 0 unless the member has co-existent moderate-to-severe plaque psoriasis. If co-existent moderate-to-severe plaque psoriasis then dosing follow plaque psoriasis indication.

Approval Length for all indications: Three months initially then up to 12 months thereafter based on clinical response.

Quantity Limits:
Plaque psoriasis – Four syringes the first month, two syringes the second month, two syringes the third month, then one syringe a month thereafter.

Psoriatic arthritis (without co-existent psoriasis) – Three syringes the first month, then one syringe a month thereafter.

Psoriatic arthritis (with co-existent psoriasis) – Four syringes the first month, two syringes the second month, two syringes the third month, then one syringe a month thereafter.

Continuation Criteria:

Psoriasis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters based on decreased total percent BSA affect.

Psoriatic arthritis – Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.

Exclusions:

1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
2. Concomitant use with other biologic medications (oral and injectable).
3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

References:


Criteria updated: 5/2019
### Non Formulary

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVALISSE</td>
<td>fostamatinib</td>
</tr>
<tr>
<td>DOPTELET</td>
<td>avatrombopag</td>
</tr>
</tbody>
</table>

### CRITERIA FOR COVERAGE/NON-COVERAGE

**TAVALISSE** is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. TAVALISSE is available as an oral tablets in strengths of 100 mg or 150 mg.

**Doptelet** is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

**TAVALISSE** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by, or in consultation with, a hematologist.
2. Documentation submitted supporting the member is clinically diagnosed with chronic immune thrombocytopenia. “Chronic” is defined as 12 months or longer.
3. Member is age 18 years of age or older.
4. Documentation of trial and failure of, intolerance to, or contraindication, to one of the following:
   - Corticosteroids such as oral prednisone or dexamethasone
   - Intravenous immunoglobulin (IVIG) or Anti-Rh(D)
   - Splenectomy or is not a surgery candidate
5. Documentation the member has an increased risk for bleeding or has bleeding symptoms present.
6. Baseline lab documentation of platelet count that is low (< 30,000/µL).
7. Baseline hepatic lab documentation is submitted and the requested dosing is consistent with hepatic function.

**DOPTELET** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Prescribed by or in consultation with, a hematologist, hepatologist, gastroenterologist, infectious disease physician or transplant specialist physician.
2. Member is age 18 years of age or older.
3. Documented submitted supporting diagnosis of chronic liver disease and baseline Child-Pugh score.

4. Documentation submitted supporting diagnosis of thrombocytopenia and lab documentation of baseline platelet count < 50,000 µL.

5. Documentation submitted supporting the member is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy and the procedure will not be any of the following:
   - Cosmetic surgery/procedure
   - Neurosurgical intervention
   - Thoracotomy
   - Laparotomy
   - Organ resection

6. The appropriate dose and dosing of tablets is requested consistent with the FDA labeled dosage and administration based on the submitted baseline platelet count (Table 1).

Table 1 – Dose and Duration of Tavalisse

<table>
<thead>
<tr>
<th>Platelet Count (x10^9/L)</th>
<th>Once Daily Dose</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 40</td>
<td>60 mg (3 tablets)</td>
<td>5 days</td>
</tr>
<tr>
<td>40 to less than 50</td>
<td>40 mg (2 tablets)</td>
<td>5 days</td>
</tr>
</tbody>
</table>

Approval Length:
Tavalisse – Three months initially then up to every 6 months based on clinical response.
Doptelet – One month only per 3 month period.

Quantity Limits:
Tavalisse – Up to 60 tablets for a 30 day supply.
Doptelet – If 60 mg prescribed then 15 tablets approvable, if 40 mg prescribed then 10 tablets total approvable.

Continuation Criteria:
Tavalisse -
1. Documentation submitted supporting a response to treatment with a platelet count of at least 50,000/µL but less than 200,000/µL. (Response rates should be seen at least 1 week after initiation of treatment with a maximum response seen at 2 weeks).  If no response by 12 weeks of treatment in terms of platelet count not increasing to a level sufficient to avoid clinically important bleeding then continuation is not approvable.
2. Documentation submitted supporting absence of unacceptable toxicity or adverse reactions from the drug. Examples include elevated liver enzymes, neutropenia, diarrhea and uncontrolled hypertension. If any are present then documentation has been submitted addressing these toxicities and adverse reactions.
**Exclusions:**
1. Tavalisse being used in an attempt to only normalize platelet counts. The goal of treatment is to prevent bleeding and to achieve a safe, but not necessarily normal, platelet count.
2. Combination use with romiplostim (Nplate).

**References:**

Criteria effective 10/01/2018; last reviewed July 2019
<table>
<thead>
<tr>
<th>Covered Products</th>
<th>Approved generic or brand name</th>
</tr>
</thead>
<tbody>
<tr>
<td>testosterone injection (cypionate or enanthate)</td>
<td>Depo-testosterone/Delatestryl</td>
</tr>
<tr>
<td>testosterone topical 1%, 1.62% gel (pkts and pump)</td>
<td>Androgel 1%</td>
</tr>
<tr>
<td>testosterone topical solution</td>
<td>Axiron</td>
</tr>
<tr>
<td>ANDRODERM PATCH</td>
<td>testosterone</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

First-line: Testosterone cypionate or testosterone enanthate injectable  
Second-line: Generic testosterone topical 1% or 1.62% gel (packets or pump) or generic topical solution  
Third-line: Androderm  

**Testosterone replacement therapy** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

**Criteria for Males with hypogonadism:**

Documentation supporting of failure of or intolerance to testosterone cypionate injection OR Member has needle phobia to a degree that it meets *DSM-V-TR 300.29* (Specific Phobia) is required for approval of second-line agents (Generic testosterone topical 1% or 1.62% gel (packets or pump) or generic topical solution) and third line agents (Androderm)

1. Members must be clinically diagnosed with documentation with one of the following: (Note: If member is new to plan and has been on testosterone therapy for hypogonadism, documentation supporting diagnosis and labs are required. Stopping testosterone therapy (2-6 weeks) and retesting of hypogonadism may be required).
   a. Primary hypogonadism (Klinefelter syndrome, cryptorchidism, orchiectomy, myotonic dystrophy, gene mutation, chromosomal abnormalities) or acquired (bilateral torsion, chemotherapy, radiation to testes, HIV infection)
   b. Secondary hypogonadism (Kallmann Syndrome, pituitary injury from tumors, trauma or radiation, Men receiving high doses of glucocorticoids, Osteoporosis or low trauma fracture, hyperprolactinemia, Severe obesity)
   c. Diagnosis of hypogonadism in men with androgen deficiency consistent with at least two clinical symptoms  
      - Specific symptoms may include:
        - Incomplete sexual development
        - Very small (especially < 5ml) or shrinking testes
        - Reduced sexual desire and activity, fewer spontaneous erections
        - Breast discomfort/gynecomastia
• Loss of body hair, low trauma fracture, low bone mineral density, height loss
• Hot flashes/sweating

- Less specific symptoms include:
  • Fatigue, depressed mood, poor concentration
  • Decreased energy, motivation, initiative, self confidence
  • Increased body fat, body mass index

2. Baseline lab must be submitted prior to initiation of therapy:
   a. At least two baseline serum total testosterone levels (less than 264 ng/dl or below reference range) drawn between 8AM and 10AM at least weeks a part within 30 days.
      - If both serum testosterone levels are near or below lower limit of normal measure LH/FSH to determine if primary or secondary hypogonadism is present.
        • Primary hypogonadism: Elevated LH and FSH levels
        • Secondary hypogonadism: Low or inadequately normal LH and FSH levels

   b. Free or bioavailable testosterone levels (less than 50 pg/mL (<5ng/dL or < 0.17 nmol/L) or less than lab reference range) are acceptable in place of total testosterone if member has a condition that may alter sex hormone binding globulin (SHBG) levels (e.g., elderly or obese, liver or HIV disease, medications (e.g., anabolic steroids, progestins, anticonvulsants), thyroid disease or if total testosterone is around lower limit of the normal range.

   **Note:** If a low testosterone level has been established, further laboratory testing is used to determine whether the hypogonadism is related to a primary testicular disorder (hypergonadotropic hypogonadism) or to pituitary disease (hypogonadotrophic hypogonadism). In patients with signs and symptoms indicative of hypogonadism, determining luteinizing hormone (LH) and follicle-stimulating hormone (FSH) levels together with the initial testosterone level is usually most efficient.

   **Note:** Testosterone levels vary from hour to hour. Periodic declines below the normal range can occur in some otherwise normal men. An overall diurnal rhythm is also present, the highest levels of circulating testosterone occurring during the early morning hours. Therefore, testosterone levels should be determined in the morning, and studies should be repeated in patients with subnormal levels, especially those with no definite signs or symptoms of hypogonadism.

**Exclusions** for male testosterone replacement therapy:
1. Treatment of “age-related hypogonadism” or “late-onset hypogonadism” alone (age 65 years and older with low testosterone levels). 6
   Note: Prostate cancer screening and monitoring should be considered for male age 55 to 69 years with low testosterone levels with good health and life expectancy of >10 years or for male age <40 years who are at increased risk for cancer such as African-American and man with first-degree male relative with prostate cancer.

2. Hematocrit >48%.
3. Active prostate or breast cancer
4. Unevaluated PSA >4 ng/ml or a PSA >3 ng/ml in individuals with risk factors for prostate cancer
5. Severe lower urinary tract symptoms (LUTS)
6. Uncontrolled congestive heart failure (CHF), severe untreated obstructive sleep apnea (OSA), severe liver or renal impairment, history of anabolic steroid abuse or dependence.

Initial Approval length for hypogonadism in males: 6 months

Continuation of therapy based on adherence, improvement in symptoms and testosterone levels:
1. Total testosterone levels (within 3-6 months) that are within reference range testosterone levels based on symptoms and dose adjustments. If testosterone levels are more than 700 ng/dl or above upper limits of lab reference range documentation that the dose will be adjusted must be submitted.

2. Member had improvement in clinical symptoms and has been adherent to regimen (i.e., More than 4-5 missed fills or doses in 3-4 months) OR justification has been provided.

Continuation approval length: 12 months.

Criteria for Males with Delayed Puberty (testosterone enanthate injection only):
1. Diagnosis of Delayed puberty (adolescent males).
   Note: Testosterone is to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief occasional treatment with conservative doses may be justified if these patients do not respond to psychological support. Discuss the potential adverse effect on bone maturation with the patient and parents prior to androgen administration. To assess the effect of treatment on the epiphyseal centers, obtain an x-ray of the hand and wrist to determine bone age every 6 months.
Criteria for Females (testosterone enanthate injection only):

1. Diagnosis of inoperable metastatic breast cancer in woman who is 1 to 5 years postmenopausal AND patient had an incomplete response to other therapy for metastatic breast cancer OR
2. Diagnosis of breast cancer in pre-menopausal woman who has benefited from oophorectomy and is considered to have a hormone-responsive tumor.

Criteria for diagnosis of Gender Dysphoria (testosterone cypionate injection only):

1. Prescribed for female-to-male gender reassignment
2. Age 16 years and older
3. For age less than 16 years, member has been given informed consent and parent or other caretaker/guardians have consented to treatment and are able to support patient thru treatment.

**Testosterone lab testing is NOT required if patient has a diagnosis of Gender Dysphoria.

Initial approval length: 12 months.

Continuation Criteria:

Documentation confirming positive response and that there are no contraindications to therapy.

Continuation approval length: 12 months.

References:


Criteria revised: 06/2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRAVATAN Z</td>
<td>travoprost 0.004%</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Travatan Z** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has diagnosis of Open-angle glaucoma or ocular hypertension AND
2. Member had trial and failure of latanoprost (generic Xalatan) or has contraindication.

Initial/continuation Approval duration: 12 months.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

References


Criteria last reviewed and updated: 04/2019
**CRITERIA FOR COVERAGE/NON-COVERAGE**

*Tremfya* is an interleukin-23 blocker indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

*TREMФYA* will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Plaque Psoriasis (Adult)**
   a. Prescribed by or in consultation with a dermatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of **moderate to severe** plaque psoriasis with ≥ 10% of body surface area (BSA) affected.

   *Note: An exception to the ≥ 10% of BSA requirement and to the below criteria are areas with moderate to severe plaque psoriasis localized to the face, nails, or genitalia that has failed use with low potency corticosteroids.*

   e. Documentation member has failed topical therapy for a trial of at least 90 days and includes two of the following verified by prescription claims history:
      i. Calcipotriene (generic for Dovonex) topical preparations
      ii. Medium-to-high potency corticosteroids
         *Note: For areas of the scalp either fluocinonide or clobetasol in a foam, solution, or shampoo can be utilized. For facial or skin fold areas a low potency hydrocortisone is sufficient.*
      iii. Tazorac topical gel 0.05%
      iv. Tacrolimus 0.1% (prior authorization required) ointment
      v. Coal tar preparations such as coal tar shampoo
   f. Member has failed one of the following therapies for a trial of at least 90 days verified per prescription claims history unless documentation submitted that supports intolerance or contraindication:
      i. Methotrexate oral tablets
      ii. Cyclosporine oral capsules
   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both *Humira* (adalimumab) and *Enbrel* (etanercept).
h. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of at least three of the following:

- Cimzia (certolizumab)
- Cosentyx (secukinumab)
- Otezla (apremilast)
- Siliq (brodalumab)
- Infliximab (biosimilar to Remicade)

j. Documentation submitted supporting Tremfya will be self-administered by the member at a maintenance dosing interval of no less than every 8 weeks after the initial dosing of one injection at Week 0 and at Week 4.

**Approval Length:** Six months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits:**

- Initial dosing the first month: Two 100 mg prefilled syringes to be administered at Week 0 and Week 4.
- Maintenance dosing: One 100 mg prefilled syringe every 8 weeks.

**Continuation Criteria:** Documentation submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters based on decreased total percent BSA affected.

**Exclusions:**

1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
2. Concomitant use with other biologic medications (oral and injectable).
3. The following is a list of acceptable contraindications for the use of methotrexate:

   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

**If all criteria met and approval is granted, medication will only be dispensed by a defined specialty pharmacy vendor at the discretion of Steward Health Choice**

**References:**


Criteria updated: 5/2019
TRETINOIN will be considered for coverage under the pharmacy benefit program when the following criteria are met:

**For patients 25 years of age or younger, tretinoin is available without a prior authorization.

Patients who are 26 years of age or older and meet the following criteria:

1. Documented diagnosis of acne vulgaris.
2. Documentation of trial and failure of, intolerance, or contraindication to OTC Differin 0.1% gel.

**Approval Length:** 12 months

**Exclusions:** Use for cosmetic purposes such as to reduce the appearance of wrinkles or age spots or to improve photoaged skin.

References:

<table>
<thead>
<tr>
<th>Covered Product</th>
<th>Reference Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>tretinoin cream (0.025%, 0.05%, 0.1%)</td>
<td>Retin-A, Avita, Refissa, Atralin</td>
</tr>
<tr>
<td>tretinoin gel (0.01%, 0.025%, 0.05%)</td>
<td></td>
</tr>
</tbody>
</table>

CRITERIA FOR COVERAGE/NONCOVERAGE
**Nonformulary**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ULORIC</td>
<td>febuxostat</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**ULoric** is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. It is not recommended for the treatment of asymptomatic hyperuricemia.

ULoric will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Documented diagnosis of symptomatic hyperuricemia with a baseline (within the past 30 days) serum uric acid level ≥ 6 mg/dL. Symptoms defined as acute gout attack(s), tophi, and chronic gouty arthritis.
2. Member is ≥ 18 years of age.
3. Documented trial and failure, or intolerance of allopurinol in the previous 180 days up to a daily dose of at least 600 mg, or to a max dose based on any renal impairment, for at least 3 months.
   **Note:** Gradual upward titration should occur every 2 to 5 weeks for the allopurinol maintenance dose to an appropriate maximum dose for gout, in order to treat to the serum urate target appropriate for the individual patient.
   **Note:** American College of Rheumatology recommends a starting dose of allopurinol of no more than 100 mg daily and an even lower starting dose of 50 mg daily if CKD is evident.
4. Intolerance of allopurinol defined as:
   - Appearance of a skin rash or hypersensitivity reasons
   - Angioimmunoblastic lymphadenopathy
   - Granulomatous hepatitis
   - Documented continued GI distress even when taken after meals. GI distress defined as diarrhea, nausea, and vomiting.
5. Titration up to Uloric 80 mg daily requires documentation of failure to obtain serum acid level to less than 6 mg/dL after trial of Uloric 40 mg.
6. Documented trial and failure of generic Febuxostat for at least 60 days

**Approval Length:** Three months initially then up to 12 months thereafter based on clinical response.

**Quantity Limits:** Thirty tablets (30) per thirty (30) days.

**Continuation Criteria:**
1. Lab documentation submitted supports serum uric acid less than 6 mg/dL while adherent to Uloric per prescription claim history and documentation of a reduced frequency of gout attacks.

**References:**


Criteria last reviewed: 6/2019
<table>
<thead>
<tr>
<th>Nonformulary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand Name</strong></td>
</tr>
<tr>
<td>VIGAMOX OPTHALMICSOLUTION</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

Vigamox ophthalmic solution (moxifloxacin) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has diagnosis of Bacterial conjunctivitis

AND

2. Member had trial and failure of two formulary covered ophthalmic agents (ciprofloxacin, levofloxacin, or ofloxacin) or contraindication to formulary agents.

Approval Duration: Up to 30 days.

References

Criteria last reviewed and updated: 6/2019
VIIBRYD is indicated for the treatment of major depressive disorder (MDD). It is a selective serotonin reuptake inhibitor (SSRI) and 5-HT1A receptor partial agonist. The mechanism of the antidepressant effect is not fully understood.

The recommended target dosage is 20 mg to 40 mg once daily. Start with an initial dosage of 10 mg once daily for 7 days, followed by 20 mg once daily. The dose may be increased up to 40 mg once daily after a minimum of 7 days between dosage increases. Prior to initiating Viibryd members should be screened for bipolar disorder.

Viibryd will be considered for coverage under the pharmacy benefit program when all of the following criteria are met:

1. A documented diagnosis of major depressive disorder (MDD).

2. The member is over the age of 18 years old.

3. A documented trial evidenced by prescription claims history of at least 30 days and failure or intolerance supported by chart notes of all of the following formulary alternatives at a maximum therapeutic or tolerated dose: escitalopram, citalopram, fluoxetine, fluvoxamine (including extended-release), paroxetine (including extended-release), sertraline, venlafaxine (including extended-release), duloxetine (20, 30, and 60 mg), desvenlafaxine, bupropion, and mirtazapine.

Quantity limits: #30 per 30 days.

Approval Length: 12 months.
Continuation criteria:

1. Documentation member is receiving a positive clinical response.

References:


Criteria last reviewed 6/2019
**Please note: Xeljanz (non-XR) is formulary product with PA.**

**Xeljanz XR** is indicated for:
- The treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
- The treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).
- The treatment of adult patients with moderately to severely active ulcerative colitis (UC).

**XELJANZ XR** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or prescriber attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Hydroxychloroquine
      iii. Leflunomide
      iv. Sulfasalazine
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
   g. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of at least three of the following:
      - Olumiant (baricitinib)
      - Kevzara (sarilumab)
      - Actemra (tocilizumab)
• Cimzia (certolizumab)

h. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

2. **Psoriatic arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of *moderate to severe* psoriatic arthritis per chart notes or prescriber attestation.
   e. Trial and failure of one of the following therapies for at least 3 months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Leflunomide
      iii. Sulfasalazine
   f. Prescribed concomitantly with a non-biologic DMARD (methotrexate, leflunomide, or sulfasalazine).
      
      **Note:** *Per prescribing information, use of Xeljanz or Xeljanz XR as monotherapy has not been studied for psoriatic arthritis.*

   g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both *Humira* (adalimumab) and *Enbrel* (etanercept).
   h. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

3. **Ulcerative colitis**
   a. Prescribed by or in consultation with a gastroenterologist.
   b. Age ≥ 18 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of moderately to severely active ulcerative colitis.
   e. Member has failed two of the following therapies verified per prescription claims history for ≥ 3 consecutive months, unless supported intolerance or contraindication submitted.
      i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
      ii. An oral corticosteroid or controlled ileal release budesonide
      iii. A thiopurine such as azathioprine
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of *Humira* (adalimumab).
   g. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

**Approval Length:**
*Rheumatoid arthritis* – Six months initially then up to 12 months thereafter based on clinical response.
*Psoriatic arthritis* – Six months initially then up to 12 months thereafter based on clinical response.
*Ulcerative colitis* – Four months initially then up to 12 months thereafter based on clinical response.
Quantity Limits:
*Rheumatoid arthritis* – Up to 60 tablets per 30 days (twice a day dosing) of Xeljanz 5 mg or 30 tablets a day of Xeljanz XR 11 mg (one time a day dosing).
*Psoriatic arthritis* – Up to 60 tablets per 30 days (twice a day dosing) of Xeljanz 5 mg or 30 tablets a day of Xeljanz XR 11 mg (one time a day dosing).
*Ulcerative colitis* – Up to 60 tablets per 30 days of Xeljanz 5 mg or 10 mg. Xeljanz XR 11 mg is not supported for use for this diagnosis.

Continuation Criteria:
*Rheumatoid arthritis and psoriatic arthritis* – Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.
*Ulcerative Colitis* – One of the following must be met by 16 weeks of initial therapy:
1. Documentation submitted supporting symptomatic remission has occurred OR a total Mayo Disease Activity Index score of 0-2.
2. Documentation submitted supporting decrease in overall symptoms from pre-treatment baseline of all, or a majority of symptoms (weight loss, abdominal pain or tenderness, intermittent nausea or vomiting, or significant anemia).

*Note:* Per the FDA labeling for Xeljanz discontinuation should occur after 16 weeks of 10 mg twice daily, if adequate therapeutic benefit is not achieved for the diagnosis of ulcerative colitis.

Exclusions:
1. Needle phobia is not considered a clinical reason for the use of Xeljanz instead of the required alternatives unless it meets DSM-V-TR 300.29 (Specific Phobia).
2. Concomitant use with other biologic DMARD medications (oral and injectable).
3. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
4. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

References:
Criteria last reviewed/updated: 6/2019
Xeljanz is indicated for:

- The treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
- The treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).
- The treatment of adult patients with moderately to severely active ulcerative colitis (UC).

**XELJANZ** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. **Rheumatoid Arthritis**
   a. Prescribed by or in consultation with a rheumatologist.
   b. Age ≥ 18 years.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or prescriber attestation.
   e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
      i. Methotrexate
      ii. Hydroxychloroquine
      iii. Leflunomide
      iv. Sulfasalazine
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
   g. Member has documented trial and failure per prescription claim history and chart notes or documented contraindication to, or intolerance of at least three of the following:
      • Olumiant (baricitinib)
      • Kevzara (sarilumab)
      • Actemra (tocilizumab)
      • Cimzia (certolizumab)
   h. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

2. **Psoriatic arthritis**
a. Prescribed by or in consultation with a rheumatologist.
b. Age ≥ 18 years.
c. Documentation submitted member has no latent or active tuberculosis infection.
d. Documented diagnosis of moderate to severe psoriatic arthritis per chart notes or prescriber attestation.
e. Trial and failure of one of the following therapies for at least 3 months unless intolerant or contraindicated:
   i. Methotrexate
   ii. Leflunomide
   iii. Sulfasalazine
f. Prescribed concomitantly with a non-biologic DMARD (methotrexate, leflunomide, or sulfasalazine).
   
   Note: Per prescribing information, use of Xeljanz or Xeljanz XR as monotherapy has not been studied for psoriatic arthritis.

g. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of both Humira (adalimumab) and Enbrel (etanercept).
h. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

3. Ulcerative colitis
   a. Prescribed by or in consultation with a gastroenterologist.
   b. Age ≥ 18 years old.
   c. Documentation submitted member has no latent or active tuberculosis infection.
   d. Diagnosis of moderately to severely active ulcerative colitis.
   e. Member has failed two of the following therapies verified per prescription claims history for ≥ 3 consecutive months, unless supported intolerance or contraindication submitted.
      i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
      ii. An oral corticosteroid or controlled ileal release budesonide
      iii. A thiopurine such as azathioprine
   f. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of Humira (adalimumab).
   g. Recent lab documentation submitted of renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

Approval Length:
Rheumatoid arthritis – Six months initially then up to 12 months thereafter based on clinical response.
Psoriatic arthritis – Six months initially then up to 12 months thereafter based on clinical response.
Ulcerative colitis – Four months initially then up to 12 months thereafter based on clinical response.

Quantity Limits:
Rheumatoid arthritis – Up to 60 tablets per 30 days (twice a day dosing) of Xeljanz 5 mg or 30 tablets a day of Xeljanz XR 11 mg (one time a day dosing).
Psoriatic arthritis – Up to 60 tablets per 30 days (twice a day dosing) of Xeljanz 5 mg or 30 tablets a day of Xeljanz XR 11 mg (one time a day dosing).
Ulcerative colitis – Up to 60 tablets per 30 days of Xeljanz 5 mg or 10 mg. Xeljanz XR 11 mg is not supported for use for this diagnosis.

Continuation Criteria:
Rheumatoid arthritis and psoriatic arthritis – Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.

Ulcerative Colitis – One of the following must be met by 16 weeks of initial therapy:
1. Documentation submitted supporting symptomatic remission has occurred OR a total Mayo Disease Activity Index score of 0-2.
2. Documentation submitted supporting decrease in overall symptoms from pre-treatment baseline of all, or a majority of symptoms (weight loss, abdominal pain or tenderness, intermittent nausea or vomiting, or significant anemia).

Note: Per the FDA labeling for Xeljanz discontinuation should occur after 16 weeks of 10 mg twice daily, if adequate therapeutic benefit is not achieved for the diagnosis of ulcerative colitis.

Exclusions:
1. Needle phobia is not considered a clinical reason for the use of Xeljanz instead of the required alternatives unless it meets DSM-V-TR 300.29 (Specific Phobia).
2. Concomitant use with other biologic DMARD medications (oral and injectable).
3. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate.
4. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

References:

Criteria last reviewed/updated: 6/2019
**BrandName** | **GenericName**
---|---
XIFAXAN | rifaximin

### CRITERIA FOR COVERAGE/NONCOVERAGE

**Xifaxan** is a rifamycin antibacterial indicated for the treatment of travelers’ diarrhea caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older, the reduction in risk of overt hepatic encephalopathy recurrence in adults, and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. It is not to be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*.

**Xifaxan** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:

1. Member has a diagnosis of **travelers’ diarrhea caused by *E. coli*** and meets ALL of the following:
   a. Member is 12 years of age or older.
   b. Culture showing causative microorganism is *E. coli*.
   c. Member does not have fever and/or blood in the stool.
   d. Member has tried and failed an adequate course (1-3 days) of at least one oral antibiotic such as fluroquinolones (e.g., ciprofloxacin, levofoxacin, norfoxacin, ofloxacin) or azithromycin.
   e. Treatment duration for this indication does not exceed 3 days, 200 mg three times a day.

2. Member has a diagnosis to **reduce the risk of recurrent overt hepatic encephalopathy** (HE) and meets ALL of the following:
   a. Member is 18 years of age or older.

   b. Member had inadequate response, intolerance or has contraindication to lactulose therapy defined as ONE of following:
      i. Member had recurrent or persistent symptoms of HE (impaired mental status, asterixis and fatigue) or increase in ammonia levels despite receiving lactulose.
      ii. Member is having ≥ 4 loose stools per day with lactulose despite dosage reductions.
iii. Member is having recurrent or persistent HE due to non-adherence to lactulose and multiple efforts with patient education about adherence has been attempted.

b. Member will continue Lactulose with Xifaxan.
   ➢ **Note:** Per the American Association for the Study of Liver Diseases (AASLD), the data does not support the use of Xifaxan alone. Per the Xifaxan prescribing information: “In the trials of Xifaxan for HE, 91% of the patients were using lactulose concomitantly.”
   ➢ **Note:** Not tolerating the taste of lactulose is not considered a failure of lactulose therapy.

e. Approval duration for hepatic encephalopathy is 6 months, 550 mg twice daily.

3. Member has a diagnosis of moderate to severe IBS-D and meets ALL of the following:
   a. Member is 18 years of age or older.
   b. The member has had trial and failure of THREE of the following:
      i. Antispasmodic (e.g. dicyclomine, hyoscyamine).
      ii. Tricyclic antidepressant (e.g. amitriptyline, nortriptyline, imipramine, or clomipramine).
      iii. Antidiarrheal (e.g., Loperamide, cholestyramine)
      iv. Lifestyle and dietary modifications (e.g., elimination of caffeine, lactose or fructose from diet, FODMAPs, use of fiber, probiotics etc.)
   c. Approval duration for IBS-D is a max of 3 treatment courses of 550mg three times daily x 14 days = 42 days total (126 tabs). A 14 day course treatment may be repeated up to two times for recurrence of symptoms.

**Continuation for coverage criteria:**

**Hepatic Encephalopathy**

1. Member had symptomatic improvement or reduction in episodes of overt hepatic encephalopathy (HE) after starting treatment with Xifaxan.

**References:**


Criteria last updated: 6/2019
### CRITERIA FOR COVERAGE/NON-COVERAGE

**Xiidra** (lifitegrast ophthalmic solution) 5% is a lymphocyte function-associated antigen-1 (LFA-1) antagonist indicated for the treatment of the signs and symptoms of dry eye disease (DED).

**Xiidra** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Member has a documented diagnosis of dry eye disease that consists of one of the following:
   a. Dry eye syndrome
   b. Keratoconjunctivitis sicca (KCS)
   c. Dysfunctional tear syndrome
   d. Lacrimal keratoconjunctivitis
   e. Evaporative tear deficiency
   f. Aqueous tear deficiency
   g. LASIK-induced neurotrophic epitheliopathy (LNE)
2. Prescriber is an ophthalmologist, optometrist, or rheumatologist.
3. Age is 17 years or older.
4. The member has a functional lacrimal gland.
5. Documentation or prescription claim history supporting the trial and failure of two separate 30-day trials of ocular lubricating solutions or ointment.
6. Documentation of trial and failure of punctal plug use.
7. Member will not continue to use punctal plugs.
8. There is no presence of current ocular infection (e.g. herpes keratitis).
9. Member is not currently taking topical anti-inflammatory drugs.

**Approval Length:** 12 months.

**Quantity Limits:** 60 foil packets per 30 days.

**Continuation Criteria:**
1. Request continues to be prescribed by an ophthalmologist, optometrist, or rheumatologist.
2. Documentation submitted of increased tear production and improvement in DED symptoms.
3. Member has been adherent per prescription claims history.

**References:**


Criteria last updated 6/2019
**Non Formulary**

<table>
<thead>
<tr>
<th>Brand Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>XYREM</td>
<td>sodium oxybate oral solution</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NON-COVERAGE**

**XYREM** is a central nervous system depressant indicated for the treatment of the following:

- Cataplexy in narcolepsy
- Excessive daytime sleepiness (EDS) in narcolepsy

It may only be dispensed to patients enrolled in the XYREM REMS Program.

XYREM is required to be taken at bedtime while in bed and again 2.5 to 4 hours later. The dose of XYREM should be titrated to effect. The efficacy and safety of XYREM at doses higher than 9 gm/night have not been investigated, and doses greater than 9 gm/night ordinarily should not be administered.

**XYREM** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member is 7 years of age or older.
2. Prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders (sleep specialist) and is board-certified by the American Board of Sleep Medicine (ABSM).
3. Diagnosis of narcolepsy confirmed by BOTH of the following:
   a. Polysomnogram test (PSG)
      i. Results must be submitted and include confirmation that at least 6 hours of sleep time occurred during the test and REM sleep latency was ≤ 15 minutes.
      ii. Documentation included that other possible causes of excessive daytime sleepiness have been ruled out.
   b. Multiple sleep latency test (MSLT)
      i. Results must be submitted and include confirmation of mean sleep latency of ≤ 8 minutes and ≥ 2 sleep onset rapid eye movement periods (SOREMPs).
4. **One** of the following must be met (a. or b.):
   a. Documented diagnosis of symptoms of cataplexy and a 30-day trial and failure of, or contraindication or intolerance, to both of the following:
i. Adults: Modafinil or armodafinil (prior authorization required for both).

ii. Adults and pediatrics: At least two drugs from any of the following REM sleep-suppressing drug classes for cataplexy:
   (1) Tricyclic antidepressant
   (2) Selective serotonin reuptake inhibitor (SSRI)
   (3) Selective norepinephrine reuptake inhibitor (SNRI)

**Note: pediatric patients are not required to try modafinil or armodafinil as they are not approved for use in pediatric patients.**

OR

b. Documented diagnosis of excessive daytime sleepiness with a 30-day trial and failure of, contraindication or intolerance, of two central nervous system stimulants. Adults must have documented trial and failure of, contraindication or intolerance to one from each of the following (i. and ii.) and supported by prescription claim history:
   i. Adults and pediatrics: Methylphenidate, dexmethylphenidate, or dextroamphetamine.
   ii. Adults: Modafinil or armodafinil (prior authorization required for both).

**Note: pediatric patients are not required to try modafinil or armodafinil as they are not approved for use in pediatric patients.**

Approval Length: Three months initially then up to 6 months thereafter based on clinical response.

Quantity Limits: Up to 540 ml per 30 days.

Continuation Criteria:
1. Documentation submitted supports the member continues to be seen periodically by the prescribing specialist.
2. Adherence to medication as demonstrated by prescription claims history.
3. Documented decrease in cataplexy symptoms or excessive daytime sleepiness from prior to starting Xyrem.

Exclusions:
1. A member with confirmed and documented succinic semialdehyde dehydrogenase deficiency.
2. A member concomitantly using a central nervous system depressant, including alcohol, verified by prescription claims history, controlled substance report, or chart notes. CNS depressant drugs may include, but not limited to, a sedative hypnotic, a narcotic analgesic (including tramadol), a benzodiazepine or non-benzodiazepine, or carisoprodol. This applies to new and continuation Xyrem prior authorization requests.

References:
4. Food and Drug Administration (FDA) drug safety communication: warning against the use of Xyrem (sodium oxybate) with alcohol or drugs causing respiratory depression.

5. American Academy of Sleep Medicine. International Classification of Sleep Disorders. 3rd ed. 2014; (Darien, IL American Academy of Sleep Medicine)

Criteria updated: 8/2019
### CRITERIA FOR COVERAGE/NONCOVERAGE

**Zioptan (tafluprost)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has elevated intraocular pressure (IOP) related to open-angle glaucoma or ocular hypertension.
2. Member must have documented trial and failure, intolerance, or contraindication to both latanoprost and travoprost.

Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy.

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**References**

Criteria last reviewed and updated: 4/2019
### Covered products

<table>
<thead>
<tr>
<th>Covered products</th>
<th>Brand or generic Name</th>
</tr>
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<tr>
<td>zolpidem ER</td>
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<tr>
<td>zolpidem sublingual</td>
<td>INTERMEZZO</td>
</tr>
<tr>
<td>EDLUAR</td>
<td>zolpidem sublingual</td>
</tr>
<tr>
<td>ZOLPIMIST</td>
<td>zolpidem oral spray</td>
</tr>
</tbody>
</table>

### CRITERIA FOR COVERAGE/NONCOVERAGE

**Zolpidem ER** is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Available in a 6.25mg and 12.5mg dose. Maximum dose per day is 12.5mg.

**Zolpidem sublingual** is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Not indicated for the treatment of middle-of-the-night awakening when a patient has fewer than 4 hours of bedtime remaining before the planned time of waking.

**EDLUAR** is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Maximum dose per day is 10mg.

**ZOLPIMIST** is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Maximum dose per day is 10mg.

**Note:** *Zolpidem has shown modest benefit in helping people sleep. However, it has not been shown in clinical studies to improve health outcomes among people with insomnia.*

**Zolpidem ER** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member has a documented diagnosis of chronic insomnia (trouble initiating or maintaining sleep for at least three nights per week for at least three months).
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days of therapy and failure of each of the following at maximum therapeutic doses:
   - d. Zolpidem 10mg.
   - e. Temazepam 30mg.
   - f. Eszopiclone 3mg

**Zolpidem sublingual** (generic for Intermezzo) will be considered for coverage under the pharmacy benefit program when the following criteria are met:
1. The member has a documented diagnosis of chronic insomnia (trouble initiating or maintaining sleep for at least three nights per week for at least three months).
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days of therapy and failure of each of the following at maximum therapeutic doses:
   a. Zolpidem 10 mg.
   b. Temazepam 30 mg.
   c. Eszopiclone 3 mg
4. Documentation has been submitted the member is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting that interferes with daily use of non-sublingual dosage forms.

EDLUAR and ZOLPIMIST will be considered for coverage under the pharmacy benefit program when the following criteria are met:
1. The member has a document diagnosis of insomnia characterized by difficulties with sleep initiation only.
2. The member is over the age of 18 years old.
3. A documented trial of at least 30 days of therapy and failure of each of the following at maximum therapeutic doses:
   a. Zolpidem 10 mg
   b. Temazepam 30 mg
   c. Eszopiclone 3 mg
   d. Zolpidem ER
   e. Zolpidem sublingual (generic Intermezzo)
4. Documentation has been submitted the member is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting that interferes with daily use of non-sublingual dosage forms.

Quantity limits:
Zolpidem ER – #30 per 30 days
Zolpidem sublingual - #30 per 30 days
EDLUAR - #30 per 30 days
ZOLPIMIST – One 7.7ml bottle (60 metered actuations) per 30 days

Initial/continuation Approval Length:
Zolpidem ER – 12 months
Zolpidem sublingual – 12 months
EDLUAR – 3 months
ZOLPIMIST – 3 months
Continuation criteria:

1. Documentation member has been reevaluated for continued necessity and is receiving a positive clinical response evidenced by a decrease in nights per week with sleep maintenance difficulties.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Recommended Dosing per Night</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
</tr>
<tr>
<td>zolpidem ER</td>
<td>6.25 – 12.5 mg</td>
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<tr>
<td>zolpidem sublingual</td>
<td>3.5 mg</td>
</tr>
<tr>
<td>Edluar</td>
<td>5-10 mg</td>
</tr>
<tr>
<td>Zolpimist</td>
<td>5-10 mg</td>
</tr>
</tbody>
</table>

Exclusions:

1. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate) or alternate formulations of Zolpidem.

References:

3. Edluar full prescribing information. Somerset, NJ. Meda Pharmaceuticals Inc.

Criteria created 04/2019
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZORTRESS</td>
<td>Everolimus</td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**ZORTRESS® (everolimus)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The patient is 18 years of age or older
2. The prescriber is experienced in immunosuppressive therapy and management of transplant patients.
3. Member must be using Zortress for prophylaxis of one of the following and meet all individual criteria:
   A. Prevention of kidney transplant organ rejection and member meets both criteria (i) and (ii) below:
      i. The member is at low-to-moderate immunologic risk
      ii. The member is prescribed concurrent therapy with basiliximab (Simulect®), corticosteroids and reduced doses of cyclosporine.
   B. Prevention of liver transplant organ rejection and member meets both criteria (i) and (ii) below:
      i. Thirty (30) or more days have passed since the transplant procedure
      ii. The member is prescribed concurrent therapy with corticosteroids and reduced doses of tacrolimus.

Authorization will be approved for lifetime.

References
Criteria last reviewed and updated: 4/2019
<table>
<thead>
<tr>
<th>Covered Products</th>
<th>GenericName</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZYVOX oral suspension</td>
<td>Linezolid</td>
</tr>
<tr>
<td>Linezolid oral tablet</td>
<td></td>
</tr>
</tbody>
</table>

**CRITERIA FOR COVERAGE/NONCOVERAGE**

**Zyvox (linezolid)** will be considered for coverage under the pharmacy benefit program when the following criteria are met:

The member has one of the following diagnoses:

1. Community-acquired pneumonia: caused by Streptococcus pneumonia (including multi-drug resistant strains), including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible strains only).
2. Complicated skin and skin structure infections: complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by S. aureus, (methicillin-susceptible and resistant strains), Streptococcus pyogenes, or Streptococcus agalactiae.
3. Nosocomial pneumonia: caused by S. aureus (methicillin-susceptible and resistant strains), or S. pneumonia (including multi-drug-resistant strains).
4. Uncomplicated skin and skin structure infections: Caused by *S. aureus* (methicillin- susceptible strains only) or *S. pyogenes*
5. Vancomycin-resistant enterococcal infections: Vancomycin-resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia

AND

6. Current Culture and Sensitivity (C&S) in support of FDA indication

Authorization will be for duration of therapy not to exceed 28 days of therapy (including doses given in hospital, emergency room, or urgent care). Additional course of therapy will require new PA submission and clinical notes documenting response and need for additional therapy.

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