



Health Choice Arizona Medication Prior Authorization Criteria

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Health Choice Arizona Pharmacy Prior Authorization Guidelines

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Brand Name	Generic Name
ACCRUFER	ferric malitol

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

Non Formulary	
Brand Name	Generic Name
ACTEMRA	tocilizumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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.
- Adult patients with systemic sclerosis-associated interstitial lung disease.

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

- Prescribed by or in consultation with a rheumatologist.
- Age \geq 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of moderate to severe rheumatoid arthritis (RA)
- Trial and failure of one of the following therapies unless intolerant or contraindicated for \geq 3 consecutive months
 - Methotrexate
 - Hydroxychloroquine
 - Sulfasalazine
 - Leflunomide
- 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.

4. Systemic 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 systemic Juvenile Idiopathic arthritis (SJIA)/Still's disease with synovitis in at least 1 joint.
- e. Trial and failure of both Humira (adalimumab) and Enbrel (etanercept). Both require prior authorization.

5. Interstitial Lung Disease Associated with Systemic Sclerosis.

- a. Prescribed by or in consultation with a pulmonologist or rheumatologist.
- b. Age of member is ≥ 18 years old.
- c. Documentation submitted member has no latent or active tuberculosis infection.
- d. Documented diagnosis of systemic sclerosis-associated interstitial lung disease.
- e. Diagnosis is confirmed by high-resolution computed tomography.
- f. Trial and failure of **one** of the following therapies for at least 3 months unless intolerant or contraindicated:
 - a. Cyclophosphamide (PA required);
 - b. Mycophenolate mofetil
- g. Recent lab documentation submitted of hepatic function, absolute neutrophil count (ANC), and platelet count.
- h. Requested dose is consistent with the FDA labeled recommended dosing for Actemra.
- 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

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.

Interstitial Lung Disease Associated with Systemic Sclerosis — Documentation submitted supporting positive clinical response as demonstrated by $\leq 10\%$ decrease in predicated forced vital capacity (FVC) over the past year while on Actemra.

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 Health Choice****

References:

1. Actemra prescribing information. South San Francisco, CA. Genentech, Inc. Rev May 2018.
2. Singh J, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.
3. Lovell DJ, Ruperto N, et al. Adalimumab with or without Methotrexate in Juvenile Rheumatoid Arthritis. *N Engl J Med*;359:810-820 Aug 2018.
4. Ringold S, Weiss P, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. *Arthritis & Rheumatism*. Vol 65(10);Oct 2013,2499-2512.
5. Mukhtyar C, Guillevin L, et al. EULAR recommendations for the management of large vessel vasculitis. *Ann Rheum Dis*. 2009 Mar; 68(3):318-23.
6. Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomised, double-blind, placebocontrolled, phase 3 trial. *Lancet Respir Med*. 2020;8(10):963-974.
7. Kowal-Bielecka OK, Fransen J, Avouac J, et al. Update of EULAR recommendations for the treatment of systemic sclerosis. *Ann Rheum Dis*. 2017;76(8):1327-1339.

Brand Name	Generic Name
ACTIMMUNE	Interferon gamma-1b

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

1. Micromedex/DRUGDEXatwww.microdexsolutions.com.
2. Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.

Criteria Name
ADHD Medications in Children < 6 years old

CRITERIA FOR COVERAGE/NONCOVERAGE
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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. The requested medication has been prescribed by or in consultation with child psychiatrist.
3. Psychosocial issues and non-medical interventions are being addressed by the clinical team.
4. Documentation of psychosocial evaluation occurring before request for ADHD medications.
 - a. Documentation provided includes of date of evaluation and name of clinician conducting assessment.
5. 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.
6. If dose is greater than FDA approved maximum daily dose, provide details and supporting documentation.
7. 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.

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. Manufacturer Product Information
2. Pliska SR, Greenhill LL, Crismon ML, et al. The Texas children's medication algorithm project: report of the Texas census conference panel on medication treatment of childhood deficit/hyperactivity disorder. Part 1. J Am Academy Child Adolescent Psychology. 200;39(7):920-927

Criteria Name
Formulary medication Prior Authorization administrative criteria

CRITERIA FOR COVERAGE/NON-COVERAGE

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:

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.***
- iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and 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:

1. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&

2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
3. American Society of Clinical Oncology (ASCO). ASCO Guidelines, Tools, & Resources. 2017.
4. Facts & Comparisons Answers. Available at: <http://online.factsandcomparisons.com>.
5. Micromedex/DRUGDEX. Available at: www.microdexsolutions.com.
6. Arizona Health Care Cost Containment System. AHCCCS Medical Policy Manual. Policy 310-V Prescription Medications/Pharmacy Services. Rev Nov 2017.

Brand Name	Generic Name
AJOVY	<i>fremanezumab-vfrm</i>

CRITERIA FOR COVERAGE/NON-COVERAGE

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. 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)

Approval Length: Initial: Six months; Continuation: one year

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).
3. Aimovig, Ajovy, and Emgality will not be used in combination with oral CGRP inhibitor

References:

1. Ajovy prescribing information. North Wales, PA. Teva Pharmaceuticals USA, Inc. Rev Sep 2018..
2. Goadsby PJ, Reuter U, et al. A Controlled Trial of Erenumab for Episodic Migraine (STRIVE). *N Engl J Med*. 2017;377:2123-2132.
3. Dodick DW, Ashina M, et al. ARISE: A Phase 3 randomized trial of erenumab for episodic migraine. *Cephalalgia* 2018, Vol 38(6), 1026-1037.
4. Tepper S, Ashina M, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. *Lancet Neurol*. 2017;16:425-434.
5. Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Patients with Episodic or Chronic Migraine: Effectiveness and Value. ICER (Institute for Clinical and Economic Review) Draft Evidence Report. April 14, 2018.
6. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1- 211.
7. Silberstein SD, Holland S, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-1345. 30.
8. Simpson DM, Hallett M, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(19):1818-1826.

Brand Name	Generic Name
ALINIA (oral suspension, tablet)	nitazoxanide

CRITERIA FOR COVERAGE/NON-COVERAGE

Note- generic Alinia tablet 500mg (nitazoxanide) available as of 12/2020.

Alinia (nitazoxanide) oral suspension (patients 1 year of age and older) and tablets (patients 12 years and older) are indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*.

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

A. Diarrhea caused by *Giardia lamblia*

1. Alinia will be approved based on all of the following:
 - i. Diagnosis of giardiasis
 - ii. History of failure, contraindication, or intolerance to metronidazole or tinidazole
 - iii. If request is for Brand Alinia tablet, member must first trial and fail generic tablet, unless contraindicated.

B. Diarrhea caused by *Cryptosporidium parvum*

1. Alinia will be approved based on the following:
 - i. Diagnosis of cryptosporidiosis
 - ii. If request is for Brand Alinia tablet, member must first trial and fail generic tablet, unless contraindicated.

If either of the above conditions are met, the request will be approved with a 3 day duration.

Approval duration : 3 days

For continuation of therapy: ongoing documentation of successful response to the medication may be necessary along with evidence of efficacy beyond 3 days must be submitted for consideration reauthorization.

Dosage and Administration:

Children 1-3 years of age: 5mL (100mg) every 12 hours with food for 3 days.

Children 4-11 years of age: 10mL (200mg) every 12 hours with food for 3 days.

Patients 12 years of age and older: 1 tablet or 25mL (500mg) every 12 hours with food for 3 days.

Quantity Limit:

Nitazoxanide (Alinia) 500 mg tablets: 6 tablets per 3 days

Nitazoxanide (Alinia) 100 mg/ 5 ml suspension: 150 ml per 3 days

References:

1. Alinia prescribing information. Romark, Tampa, FL. April 2017.
2. Centers for Disease Control and Prevention. Parasites- Giardia. Available at: <https://www.cdc.gov/parasites/giardia/treatment.html>. Accessed March 16, 2021.
3. Centers for Disease Control and Prevention. Parasites- Cryptosporidium (also known as "Crypto"). Available at: <https://www.cdc.gov/parasites/crypto/treatment.html>. Accessed March 16, 2021.
4. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2021.

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:

1. Amitiza Prescribing information. Deerfield, IL Takeda Pharmaceuticals. Rev Aug 2017.
2. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017.
3. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 03/2017.
4. Bharucha A, Pemberton, JH, et al. American Gastroenterological Association Technical Review on Constipation. *Gastroenterology* 2013;144:218-238.

NON-FORMULARY	
Brand Name	Generic Name
AMPYRA	dalfampridine

CRITERIA FOR COVERAGE/NON-COVERAGE

Ampyra is a potassium channel blocker indicated to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

Ampyra will be considered for coverage under the pharmacy benefit program when all of the following criteria are met with documentation submitted:

1. Prescribed and requested by a neurologist.
2. Member is 18 years of age or older.
3. Member has a documented diagnosis of multiple sclerosis and has not had an exacerbation in the last 60 days.
4. Member is currently receiving concomitant treatment with a disease-modifying agent for multiple sclerosis as evidenced by prescription claims history or in medical claim history.
5. Member is ambulatory and has the ability to walk 25 feet since documentation of one baseline Timed 25-Foot Walk (T25-FW) test is required. Member cannot be bed-bound or in a wheelchair.
6. Member's baseline walking speed per a T25-FW test is done in the past 30 days and is between 8 and 45 seconds. If baseline walk speed is less than 8 seconds, member must have a baseline Expanded Disability Status Scale (EDSS) score between 4.5-6.5.
7. The baseline T25-FW test must be conducted in accordance with guidelines set by the Administration and Scoring Manual of the National Multiple Sclerosis Society. Documentation of the baseline T25-FW test must be submitted for review and be consistent with all of the following criteria:
 - a. Member must wear comfortable shoes that are consistent in style for each T25-FW test. High heel shoes cannot be worn for one test and then running shoes for the next.
 - b. Member must walk at a steady pace. Member can walk quickly but not run. If member wears an orthosis then it must be worn for each subsequent T25-FW test.
 - c. Member cannot use a wall for support during the test but can use other assistive devices which only include crutch, cane, wheeled walker, and rollator. A non-wheeled walker cannot be used.
 - d. Member cannot use the assistance of a person during the T25-FW test.
 - e. Member should walk unencumbered during the T25-FW test. Coats and purses hanging off a member should be removed before a test. A guard belt is allowed but must be consistently worn for each subsequent test.

- f. If a member cannot successfully complete a T25-FW test then another can be attempted. A maximum of only two attempts for a T25-FW tests are allowed.

8. Member does not have a current or prior history of seizures.

9. Member has a creatinine clearance greater than 50 ml/min.

Approval length: Three months initially, six months thereafter dependent on clinical response.

Continuation Criteria: After three months of initial therapy, the 25-foot walking speed should be re-assessed by a T25-FW test and be submitted for review. The T25-FW must be conducted consistently with how the baseline T25-FW was conducted prior to initiation of therapy with Ampyra and in accordance with Administration and Scoring Manual of the National Multiple Sclerosis Society as outlined in this policy. If the walking speed has not improved by at least 25% then reauthorization will not be granted. Reassessment is required every six months to evaluate continued efficacy and for continued approval.

Exclusions:

1. Use of Ampyra doses greater than 10mg twice a day or taken less than twice a day.

References:

1. Ampyra prescribing information. Hawthorne, NY. Acorda Therapeutics, Inc. Rev Sep 2017.
2. Goodman AD, Brown TR, et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. Lancet. 2009 Feb 28;373(9665):732-8.
3. Goodman AD, Brown TR, et al. A phase 3 trial of extended release oral dalfampridine in multiple sclerosis. Ann Neur. 2010 Oct;68(4):494-502.
4. Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). Neurology. 1983.
5. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Nov;33(11):1444-521.
6. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017.
7. Fischer JS, Jak AJ, et al. Administration and Scoring Manual. National Multiple Sclerosis Society. Rev Oct 2001.

Criteria Name
Antidepressants in Children < 6 years old

CRITERIA FOR COVERAGE/NON-COVERAGE

[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:

1. Arizona Department of Health Services/Division of Behavioral Health Services (ADHS/DBHS) Policy and Procedures Manual. Section 3.15: Psychotropic Medications: Prescribing and Monitoring. Rev May 2015.

2. AHCCCS Toolkit for the Management of Childhood and Adolescent Depression. Rev May 2011.
3. Bonin L, Moreland S. Overview of treatment for pediatric depression. www.UpToDate.com. Rev Oct 2017.
4. American Academy of Child and Adolescent Psychiatry (AACAP). Practice Parameter for the Assessment and Treatment of Children and Adolescents with Obsessive-Compulsive Disorder. *J Am Acad Child Adolesc Psychiatry*. 2012;51(1):98-113.
5. *2016-2017 Florida Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents* (2017). The University of South Florida, Florida Medicaid Drug Therapy Management Program sponsored by the Florida Agency for Health Care Administration (AHCA).
6. AHCCCS Medical Policy Manual. Policy 310-V Prescription medications/Pharmacy Services. Rev Feb 2017.

Brand Name	Generic Name
ANZEMET	dolasetron

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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 02/2019
2. Facts&ComparisonseAnswersat<http://online.factsandcomparisons.com>. Accessed 11/2016

Brand Name	Generic Name
AVACLYR	acyclovir ophthalmic ointment

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

Brand Name	Generic Name
BANZEL Tablets and Oral Suspension	Rufinamide Tablets and Oral Suspension

CRITERIA FOR COVERAGE/NONCOVERAGE

Note- Banzel oral suspension is now available in generic as of 11/2020.

Banzel is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in pediatric patients 1 year of age and older, and in adults.

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

I. Initial Approval Criteria (must meet all):

1. Diagnosis of Lennox-Gastaut Syndrome (LGS);
2. Member does not have Familial Short QT syndrome.
2. Member is at least 1 year of age
3. Prescribed by or in consultation with a neurologist;
4. Failure of two formulary alternatives for LGS (e.g., clonazepam, felbamate, lamotrigine, topiramate) unless all are contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 3200 mg per day.
6. If request is for Brand Banzel oral suspension, member had a trial and failure of rufinamide oral suspension (generic Banzel), unless contraindicated.

Initial duration: 12 months

II. Continuation Criteria (must meet all):

1. Currently receiving medication via pharmacy claims history
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 3200 mg per day.

Renewal duration: 12 months

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

Dosage and administration:

- Children Four Years and Older with Lennox-Gastaut Syndrome: Treatment should be initiated at a daily dose of approximately 10mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10mg/kg increments every other day to a target dose of 45mg/kg/day or 3200mg/day, whichever is less, administered in two equally divided doses. It is not known whether doses lower than the target doses are effective.
- Adults with Lennox-Gastaut Syndrome: Treatment should be initiated at a daily dose of 400-800mg/day administered in two equally divided doses. The dose should be increased by 400-800 mg/day every 2 days until a maximum daily dose of 3200mg/day, administered in two equally divided doses is reached. It is not known whether doses lower than 3200mg are effective.

References

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 02/2021
2. Banzel Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; June 2015. Available at: <https://www.banzel.com/areas/banzel/pdfs/BanzelPI.pdf>. Accessed February 05, 2021.

NONFORMULARY	
Brand Name	Generic Name
BELSOMRA	suvorexant

CRITERIA FOR COVERAGE/NON-COVERAGE

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:

1. Belsomra prescribing information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. Rev May 2016.
2. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;12(2):307-349.

Brand Name	Generic Name
BENLYSTA	Belimumab

CRITERIA FOR COVERAGE/NON-COVERAGE

The use of Benlysta by IV infusion is considered a Medical benefit and not addressed in this policy.

Benlysta is a human monoclonal antibody drug that specifically recognizes and inhibits the biological activity of B-lymphocyte stimulator, or BLyS. BLyS is a cytokine that belongs to the tumor necrosis factor (TNF) ligand family. It is expressed as a transmembrane protein on various cell types including monocytes, dendritic cells, and bone marrow stromal cells and is required for the development of B-lymphocyte cells into mature plasma B cells. Plasma B cells produce antibodies, the body's first line of defense against infection. In lupus and certain other autoimmune diseases, elevated levels of BLyS are believed to contribute to the production of autoantibodies – antibodies that attack and destroy the body's own healthy tissues. The presence of autoantibodies appears to correlate with disease severity. Preclinical and clinical studies suggest that belimumab can reduce autoantibody levels in SLE.

Benlysta has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of active, autoantibody-positive, SLE in patients who are receiving standard therapy. It was originally approved as an intravenous infusion, but a subcutaneous formulation was approved in 2017. SLE is a potentially fatal autoimmune disease that is characterized by clinical diversity, alterations in disease activity over time, and aberrations in multiple immune system components including B cells, T cells, as well as cytokines and growth factors, especially the presence of anti-nuclear antibodies (ANA) found in over 90 % of patients. Moreover, anti-double-strand deoxyribonucleic acid (anti-dsDNA) antibodies are found in 50 to 90 % of patients. The disease affects many parts of the body including the brain, heart, joints, kidneys, lungs, and skin. When SLE flares, it can present as chest pain, fatigue, fever, hair loss, rash, light sensitivity, as well as joint pain and swelling. Conventional treatments of SLE include anti-malarials (e.g., hydroxychloroquine), corticosteroids, and non-steroidal anti-inflammatory drugs.

Benlysta 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.
2. Documentation submitted of **one** of the following:
 - a. Positive autoantibody test (e.g., anti-nuclear antibody [ANA]) greater than the laboratory reference range.
 - b. Positive anti-double-stranded DNA [anti-dsDNA] test greater than the laboratory reference range.
3. Documentation submitted supporting member has failed to respond adequately to at least **two** (2) of the following standard therapies:
 - a. An antimalarial such as hydroxychloroquine.

- b. A corticosteroids such as oral prednisone or intravenous methylprednisolone.
 - c. Non-steroidal anti-inflammatory drugs (NSAIDs)
 - d. Immunosuppressives such as mycophenolate, azathioprine, or cyclophosphamide.
- 4. Documentation submitted supporting member has **one** of the following:
 - a. Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12.
 - b. British Isles Lupus Assessment Group (BILAG) A organ domain score ≥ 1 or BILAG B organ domain score ≥ 2 .
- 5. Documentation submitted supporting member does not have an active infection.
- 6. Member has not received a live vaccine within 30 days before starting or concurrently with Benlysta.
- 7. Benlysta will be administered SQ (self-injection)
- 8. Member does not have any of the following exclusion criteria:
 - a. Severe active central nervous system lupus.
 - b. Severe active lupus nephritis.

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

Continuation criteria

- 1. Member continues to meet the criteria identified in section in the initial medical necessity criteria review section including the continued use of concomitant standard therapy as per chart notes submitted and/or prescription claims history.
- 2. Adequate documentation has been submitted of disease stability and/or improvement as indicated by **one or more** of the following when compared to pre-treatment baseline:
 - a. Improvement in the SELENA-SLEDAI score of ≥ 4 points.
 - b. No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores.
 - c. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reaction, etc.

Exclusions:

- 1. Use with other biologic medications or IV cyclophosphamide has not been studied.

References:

- 1. Benlysta prescribing information. Rockville, MD. GlaxoSmithKline. Rev Jun 2018.
- 2. Gordon C, Amissah-Arthur MB, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. Rheumatol 2017 Oct 6.
- 3. NICE. Belimumab for treating active autoantibody-positive systemic lupus erythematosus: Technology Appraisal Guidance. [TA397]. Jun 2016.

4. Wallace DJ. Overview of the management and prognosis of systemic lupus erythematosus in adults. Waltham, MA. UpToDate. Rev Oct 2018.
5. Petri M, Kim MY, et al. Combined oral contraceptives in women with systemic lupus erythematosus. *N Engl J Med*. 2005;353 (suppl): 2550-2558.
6. Castrejon, O, Tani C, Jolly M, et al. Indices to assess patients with systemic lupus erythematosus in clinical trials, long-term observational studies, and clinical care. *Clin Exp Rheumatol*. 2014;32(85):S85-95.
7. Petri M. Disease activity assessment in SLE: do we have the right instruments? *Ann Rheum Dis*. 2007;66(suppl III):iii61-iii64.
8. Yee CS, Farewell V, et al. British Isles Lupus Assessment Group 2004 index is valid for assessment of disease activity in systemic lupus erythematosus. *Arthritis Rheum*. 2007 Dec;56(12):4113-9.
9. Petri M, Kim MY, et al. Combined oral contraceptives in women with systemic lupus erythematosus. *N Engl J Med*. 2005;353 (suppl):2550-2558.

Brand Name	Generic Name
BRILINTA	Ticagrelor

CRITERIA FOR COVERAGE/NONCOVERAGE

Ticagrelor, a cyclopentyltriazolopyrimidine, is indicated for thrombosis prophylaxis in the following conditions: acute coronary syndrome, history of a myocardial infarction, and percutaneous coronary intervention. Ticagrelor is also indicated for the reduction of risk of a first myocardial infarction or stroke in high-risk patients with coronary artery disease.

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

- 1.) The initial prescription is written by or in consultation with a cardiologist.
- 2.) The member has one of the following diagnoses:
 - a. Thrombosis prophylaxis for acute coronary syndrome
 - b. Thrombosis prophylaxis in patients with a history of a myocardial infarction
 - c. Thrombosis prophylaxis for percutaneous coronary intervention.
 - d. Reduction of risk of a first myocardial infarction or stroke in high-risk patients with coronary artery disease.
 - e. Reduction of risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score [NIHSS] of 5 or less) or high-risk transient ischemic attack (TIA).

General Dosage: Initiate BRILINTA treatment with a 180 mg (two 90 mg tablets) loading dose and continue treatment with 90 mg twice daily. After the initial loading dose of aspirin (usually 325 mg), use BRILINTA with a daily maintenance dose of aspirin of 75-100 mg.

- 1.) Acute coronary syndrome:
 - a. Maintenance dose = 90 mg orally twice daily beginning about 12 hours after loading dose and given in morning and evening (preferably 12 hours apart) for 1 year after acute coronary syndrome event, then 60 mg twice daily (FDA dosage).
 - b. Duration: Continue for at least 12 months; use beyond 12 months may be considered in select patients; discontinuation after 6 months may be considered in patient with newer generation drug-eluting stent and high bleeding risk (guideline dosage).
- 2.) Myocardial infarction: (1 year or more after event) 60 mg orally twice daily in combination with aspirin 75 to 100 mg orally daily
- 3.) Percutaneous coronary intervention:
 - a. Maintenance dose: 90 mg orally twice daily beginning about 12 hours after loading dose and given in the morning and evening (preferably 12 hours apart) for 1 year after acute coronary syndrome event, then 60 mg twice daily (FDA dosage)
- 4.) Coronary artery disease (stable) and high risk for ischemic cardiovascular events, primary prevention:

a. Maintenance dose: 60 mg twice daily in combination with aspirin; continue ticagrelor and aspirin indefinitely

5) Reduction of risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score [NIHSS] of 5 or less) or high-risk transient ischemic attack (TIA):

a. Loading dose: 180mg orally once

b. Maintenance: 90mg twice daily **for up to 30 days**

Approval Length: 12 months, all indications except for Reduction of risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score [NIHSS] of 5 or less) or high-risk transient ischemic attack (TIA).

Continuation Criteria:

- 1.) Consistent prescription claim history. If non-adherence is observed, chart notes documenting that the compliance issue has been addressed and/or the reasons for the member's non-compliance.
- 2.) Documentation that the member is tolerating the medication without side effects.
- 3.) For acute coronary syndrome: A reduction in thrombotic cardiovascular events.

Exclusions:

- 1.) Active pathological bleeding
- 2.) History of intracranial hemorrhage
- 3.) Maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor and should be avoided.
- 4.) Avoid concomitant use with strong CYP3A inducers (eg, rifampin, dexamethasone, phenytoin, carbamazepine, and phenobarbital).
- 5.) Avoid concomitant use with simvastatin and lovastatin doses greater than 40 mg
- 6.) Avoid concomitant use with strong CYP3A inhibitors (eg, atazanavir, clarithromycin, indinavir, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, and voriconazole)
- 7.) Concomitant use with Sporanox (itraconazole) and Defitelio (Defibrotide) is contraindicated.
- 8.) Avoid use with severe hepatic impairment
- 9.) If intolerable dyspnea occurs, consider alternative antiplatelet therapy
- 10.) Surgery: When possible, interrupt therapy 5 days prior to procedure with major risk of bleeding. Resume therapy upon hemostasis

Brand Name	Generic Name
BYNFEZIA self-injectable pen	octreotide

CRITERIA FOR COVERAGE/NON-COVERAGE

Bynfezia Pen is a somatostatin analogue FDA indicated for:

- Reduction of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- Treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients
- Treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients

Bynfezia is available as a prefilled pen for self-administrated subcutaneous injection with a starting dose of 50 mcg three times daily up to a typical dose of 100 mcg three time a day. Starting dose will require two pens a month up to four pens a month for the typical dose.

Initial approval criteria:

Acromegaly

1. Prescribed by, or in consultation with an endocrinologist.
2. Member is 18 years of age or older.
3. Documentation confirming diagnosis of **acromegaly** with laboratory report based on laboratory reference range of high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender.
4. Documentation of inadequate or partial response to surgery or radiotherapy, or clinical reason submitted supporting clinically why surgery or radiotherapy is not an option.
5. Documentation of clinical failure at a maximally tolerated dose, intolerance to, or contraindication to, bromocriptine.
6. If mild symptoms, documentation of clinical failure at a maximally tolerated dose after adequate 30 day trial, intolerance to, or contraindication to, **cabergoline** oral tablets or other dopamine agonist.
7. Requested dose and dosing will not exceed 300 mcg per day (100 mcg three times a day).

Severe diarrhea/flushing associated with Metastatic Carcinoid Tumors or VIPoma

1. Documented diagnosis of **advanced metastatic carcinoid tumor** or **VIPoma** with presence of severe diarrhea or flushing.
2. Requested dose and dosing will not exceed 750 mcg per day.

Initial and Continuation Approval Duration: 6 months

Continuation criteria:

Acromegaly –

1. Documentation submitted supporting decrease or normalization in IGF-1 level since initiation of therapy.

Metastatic carcinoid Tumors or VIPoma -

1. Documentation submitted supporting improvement or stabilization in clinical signs and symptoms since initiation of therapy.

Quantity Limits: Up to a maximum of 4 pens per 30 days. Maximum dosing interval per day of three times daily with either 50 mcg or 100 mcg.

References:

1. Bynfezia prescribing information. Cranbury, NJ. Sun Pharmaceutical Industries. Rev Jan 2020.
2. Melmed S, Katznelson L, et al. Treatment of acromegaly. Waltham, MA. UpToDate, Inc. Rev Apr 2020.
3. Katznelson L, Laws ER, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* Nov 2014. 99(11):3933-3961.
4. Chan JA, Kulke M. Metastatic well-differentiated gastrointestinal neuroendocrine (carcinoid) tumors: Systemic therapy options to control tumor growth. Waltham, MA. UpToDate, Inc. Rev Aug 2020.

Brand Name	Generic Name
BEVESPI AEROSPHERE	glycopyrrolate/formoterol
STIOLTO RESPIMAT	tiotropium/olodaterol

CRITERIA FOR COVERAGE/NON-COVERAGE

Bevespi Aerosphere is a combination of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta₂-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.

Stiolto 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:

1. Bevespi Aerosphere prescribing information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Rev Jun 2017.
2. Stiolto Respimat prescribing information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. Rev May 2018.
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of chronic obstructive pulmonary disease: 2018 Report. www.goldcopd.org.

Nonformulary	
Brand Name	Generic Name
Soma	Carisoprodol

CRITERIA FOR COVERAGE/NONCOVERAGE

Member must meet following criteria for approval:

- Diagnosis of pain related to acute musculoskeletal conditions

AND

- Member had failure of or contraindication to ALL formulary agents such as baclofen 10mg, 20mg tablets, tizanidine tablets, methocarbamol, cyclobenzaprine 10mg, and chlorzoxazone.

AND

- Carisoprodol is prescribed for duration of therapy not exceeding 2-3 weeks. Provider must submit rationale for duration of therapy beyond 3 weeks.

(Per package insert: To reduce abuse potential, carisoprodol duration of therapy should not exceed 2 to 3 weeks; data supporting efficacy for prolonged periods are not available).

AND

- Member is not taking opioids or other CNS depressants.

Approval duration: 3 weeks (120 tablets per 30 days).

References:

1. Product Information: SOMA oral tablets, carisoprodol oral tablets. Meda Pharmaceuticals Inc. (per FDA), Somerset, NJ, 2013.
2. US Food and Drug Administration (FDA): Drug Safety Communications: FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks. US Food and Drug Administration (FDA). Silver Spring, MD. 2017. Available from URL: <https://www.fda.gov/media/107888/download>. Accessed on March, 2020.

Covered Product	Reference Brand Name
Celecoxib	CELEBREX

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:

Celecoxib 50mg, 100mg, or 200mg: Thirty (30) day trial of a formulary oral NSAID in the last 90 days.

Celecoxib 400mg:

- 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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 01/2019
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 03/2017

CGRP - Non Formulary	
Brand Name	Generic Name
AIMOVIG	erenumab-aooe
EMGALITY	<i>galcanezumab-gnlm</i>

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 ≥ 18 years of age.
3. Documented trial and failure of formulary Ajovy.
4. 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: Initial: Six months; Reauthorization: one year

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).
3. Aimovig and Emgality will not be used in combination with oral CGRP inhibitor.

References:

1. Aimovig prescribing information. Thousand Oaks, CA. Amgen Inc. Rev May 2018.
2. Goadsby PJ, Reuter U, et al. A Controlled Trial of Erenumab for Episodic Migraine (STRIVE). *N Engl J Med*. 2017;377:2123-2132.
3. Dodick DW, Ashina M, et al. ARISE: A Phase 3 randomized trial of erenumab for episodic migraine. *Cephalalgia* 2018, Vol 38(6), 1026-1037.
4. Tepper S, Ashina M, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. *Lancet Neurol*. 2017;16:425-434.
5. Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Patients with Episodic or Chronic Migraine: Effectiveness and Value. ICER (Institute for Clinical and Economic Review) Draft Evidence Report. April 14, 2018.
6. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1- 211.
7. Silberstein SD, Holland S, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-1345. 30.
8. Simpson DM, Hallett M, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(19):1818-1826.
9. Emgality prescribing information. Indianapolis, IN. Eli Lilly and Company. Rev June 2019.
10. <https://www.uptodate.com/contents/cluster-headache-treatment-and-prognosis/>

CGRP - Oral
Brand Name
UBRELVY
REYVOW
NURTEC

CRITERIA FOR COVERAGE/NON-COVERAGE

Initial criteria:

- 1) Failure to respond to or tolerate ALL formulary oral triptans, as determined by either health care provider attestation or a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Treatment Optimization Questionnaire [mTOQ], Migraine Assessment of Current Therapy [Migraine-ACT], Patient Perception of Migraine Questionnaire-Revised [PPMQ-R], Functional Impairment Scale [FIS], Patient Global Impression of Change [PGIC])

OR

- 2) Documented contraindication to triptans
- 3) Member is currently established on a prophylactic therapy, which will be continued. (b-blocker, anti-depressant, AED, Botox. **Allergan is currently conducting a phase I study to determine safety/interaction of using Ubrelvy in combination with a prophylactic CGRP, Emgality/Ajovy/Aimovig. No current interaction or contraindication is noted in drug information, but until additional information is available, would suggest denial for concomitant use of acute and prophylactic CGRP combination). I have not found any information showing contraindication of oral CGRP with Botox. Unless others have seen otherwise, would suggest approval.
- 4) Documentation abortive medication is prescribed within FDA approved limits, adjusted for drug interactions as necessary, and no contraindicating drug interactions are present.

****Reviewer note/reference:**

Ubrelvy: Adults: 50 or 100 mg PO as a single dose. A second dose may be taken at least 2 hours after the initial dose if needed. Max: 200 mg/day. The safety of treating more than 8 migraines within 30 days has not been established.

Nurtec: Adults: 75 mg PO as a single dose. Max: 75 mg/day. The safety of treating more than 15 migraines in a 30-day period has not been established. Coadministration of certain other drugs may need to be avoided or dosage adjustments may be necessary; review drug interactions

Reyvow: Adults: 50, 100, or 200 mg PO as a single dose. Do not exceed more than 1 dose in 24 hours. A second dose has not been shown to be effective for the same migraine attack. The safety of treating an average of more than 4 migraine attacks within 30 days has not been established

Several major/severe drug interactions/contraindications are noted for Ubrelvy/Nurtec and they are not recommended to be used in combination with strong Cyp3A4 inhibitors. Dosing adjustments are also recommended if Ubrelvy/Nurtec is used in combination with Cyp3A4 inducers, and weak to moderate Cyp3A4 inhibitors.

Several p-GP interactions are also noted for Reyvow (atorvastatin, digoxin, cyclosporine, etc), and concomitant use is not recommended.

Initial approval x 3 months

Renewal Criteria:

- 1) Documentation of a decrease in average monthly migraine frequency and clinical assessment of improvement by a health care provider, or patient response to a validated acute treatment outcome questionnaire.
- 2) Continued adherent use of prophylactic medication

Reauthorization: Approve x 12 months

References:

1. Aimovig prescribing information. Thousand Oaks, CA. Amgen Inc. Rev May 2018.
2. Goadsby PJ, Reuter U, et al. A Controlled Trial of Erenumab for Episodic Migraine (STRIVE). *N Engl J Med*. 2017;377:2123-2132.
3. Dodick DW, Ashina M, et al. ARISE: A Phase 3 randomized trial of erenumab for episodic migraine. *Cephalalgia* 2018, Vol 38(6), 1026-1037.
4. Tepper S, Ashina M, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. *Lancet Neurol*. 2017;16:425-434.
5. Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Patients with Episodic or Chronic Migraine: Effectiveness and Value. ICER (Institute for Clinical and Economic Review) Draft Evidence Report. April 14, 2018.
6. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1- 211.
7. Silberstein SD, Holland S, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-1345. 30.
8. Simpson DM, Hallett M, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(19):1818-1826.
9. Emgality prescribing information. Indianapolis, IN. Eli Lilly and Company. Rev June 2019.
10. <https://www.uptodate.com/contents/cluster-headache-treatment-and-prognosis/>

NON FORMULARY	
Brand Name	Generic Name
CIMZIA	Certolizumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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 \geq 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. 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 \geq 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. Hydroxychloroquine
 - iii. Leflunomide
 - iv. 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 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 $\geq 10\%$ of body surface area (BSA) affected.

Note: *An exception to the $\geq 10\%$ 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
- 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
- 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.

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. 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 Health Choice****

References:

1. Cimzia prescribing information. Smyrna, GA. UCB, Inc. Rev Jun 2018.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.
4. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010.

5. Ward MM, Deodhar A, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology*. 2015.
6. Van der Heijde D, Ramiro S, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Annals of the Rheumatic Diseases*. 2017;76:978-991.
7. Singh J, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.

Covered Product	Brand Name
Cinacalcet	SENSIPAR

CRITERIA FOR COVERAGE/NONCOVERAGE
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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, sevelamer)
 - ii. A vitamin D analog (e.g. calcitriol, doxercalciferol)
 - 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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 03/2017

Nonformulary	
Brand Name	Generic Name
CINRYZE	C1 esterase inhibitor [human]
HAEGARDA	C1 esterase inhibitor [human]

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. 17 α – 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

The MedWatch form for healthcare professionals can be found at:

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:

1. Haegarda prescribing information. Kankakee, IL. CSL Behring LLC. Rev Oct 2017.
2. Cinryze prescribing information. Exton, PA. ViroPharma Biologics, Inc. Rev Dec 2016.
3. Bowen T, Cicardi M, et al. 2010 International consensus algorithm for the diagnosis, therapy and management of hereditary angioedema. *Allergy Asthma Clin Immunol*. 2010;6(1):24.
4. Craig T, Aygören-Pürsün E, et al. WAO Guideline for the Management of Hereditary Angioedema. *World Allergy Organ J*. 2012 Dec;5(12):182-99.

5. Zuraw BL, Bernstein JA, et al. A focused parameter update: hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor associated angioedema. *J Allergy Clin Immunol*. 2013 Jun;131(6):1491-3.
6. Zuraw BL, Banerji A, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. *J Allergy Clin Immunol Pract*. 2013 Sep-Oct;1(5):458-67.

Covered Product	Brand Name
clobazam	ONFI

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.

References

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
2. Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 11/2016

Criteria name	
COMPOUNDS	

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.

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 RBHA 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

1. Micromedex/DRUGDEX at www.microdexsolutions.com.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.

Criteria Name
Concomitant Antipsychotic Therapy

CRITERIA FOR COVERAGE/NONCOVERAGE
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Concomitant Antipsychotic Treatment 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

1. Micromedex/DRUGDEX at www.microdexsolutions.com.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.

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
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.

Criteria Name
Concomitant Long Acting Opioid Therapy
Applies to all long acting opioids (formulary and non-formulary agents)
Formulary products include: Butrans, Fentanyl patches, Morphine Sulfate ER tablets, Tramadol ER tablets, and Xtampza ER capsules

CRITERIA FOR COVERAGE/NONCOVERAGE
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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.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.

Criteria Name
Concomitant Short Acting Opioid Therapy
Applies to all Short Acting Opioids (formulary and non-formulary agents)

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.

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

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.

Brand Name	Generic Name
CORLANOR	ivabradine

Corlanor is in a class of medications called hyperpolarization-activated cyclic nucleotide-gated (HCN) channel blockers.

FDA Indications:

1. To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction < 35%, who are in sinus rhythm with resting heart rate >70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.
2. Treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients ages 6 months and older, who are in sinus rhythm with an elevated heart rate.

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

May be authorized for members 18 years of age or older when the following criteria are met:

1. Diagnosis of stable symptomatic chronic heart failure (New York Heart Association (NYHA) Class II-III)
2. Left ventricular ejection fraction (LVEF) is less than or equal to 35%
3. Member is in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute
4. Continuation of therapy with maximally tolerated beta-blocker, or there is intolerance or contraindication to beta-blockers
5. Continuation of therapy with angiotensin-converting-enzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto, or there is intolerance, or contraindication to angiotensin-convertingenzyme inhibitor (ACEI)/Angiotensin Receptor Blockers (ARB), or Entresto
Note: Entresto requires Prior Authorization

6. Provider attestation that no contraindications to treatment exist:
 - a. Acute decompensated heart failure
 - b. Blood pressure less than 90/50 mmHg
 - c. Pacemaker dependent (for example: heart rate maintained exclusively by pacemaker)
 - d. Sick sinus syndrome, sinoatrial block of third-degree AV block (unless functioning demand pacemaker is present)
 - e. Severe hepatic impairment (Child-Pugh class C)

May be authorized for pediatric members 6 months of age or older when the following criteria are met:

1. Diagnosis of heart failure due to dilated cardiomyopathy
2. Member is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minutes
3. Provider attestation that no contraindications to treatment exist:
 - a. Acute decompensated heart failure
 - b. Blood pressure less than 90/50 mmHg
 - c. Pacemaker dependent (for example, heart rate maintained exclusively by pacemaker)
 - d. Sick sinus syndrome, sinoatrial block or third-degree AV block (unless functioning demand pacemaker is present)
 - e. Severe hepatic impairment (Child-Pugh class C)

Initial approval: 6 months

Continuation criteria:

1. Member is responding to treatment
2. Heart rate is within recommended range for continuation of maintenance dose
(for example, 50-60 beats per minutes, or dose adjusted accordingly to achieve goal).

Renewal approval: 1 year

Quantity Limit:

Adults and pediatrics: 60 tablets per 30 days

Oral solution for pediatrics: 120 ampules per 30 days

References:

3. Yancy CW et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure Circulation: 2017.
http://www.onlinejacc.org/content/accj/70/6/776.full.pdf?_ga=2.179733604.1964533065.1574204551-936785029.1560984365. Accessed March 15, 2021.
4. Corlanor (ivabradine) [package insert]. Thousand Oaks, CA; Amgen Inc.; Revised April, 2019. Retrieved from https://www.pi.amgen.com/~media/amgen/repositorysites/pi-amgencom/corlanor/corlanor_pi.pdf. Accessed March 15, 2021.
5. Micromedex/DRUGDEX at www.micromedexsolutions.com. Accessed 03/2021

Nonformulary	
Brand Name	Generic Name
COSENTYX	secukinumab

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)

- Prescribed by or in consultation with a dermatologist.
- Age ≥ 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of **moderate to severe** plaque psoriasis with $\geq 10\%$ of body surface area (BSA) affected.

Note: *An exception to the $\geq 10\%$ 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.*

- 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. Member has documented trial and failure per prescription claims history and chart notes or documented contraindication to, or intolerance of **Humira** (adalimumab), **Enbrel** (etanercept), and Otezla (apremilast).
- 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 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 **Humira** (adalimumab), **Enbrel** (etanercept), Otezla (apremilast) and Xeljanz IR.
- g. Current weight is documented and dated within the past 90 days and resulting dose calculated is consistent with the FDA labeled dosing.
- h. 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 \geq 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.

Ankylosing spondylitis – Documentation submitted supporting decrease in at least **one** of the following: 1) Back pain; 2) 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 Health Choice****

References:

1. Cosentyx prescribing information. East Hanover, NJ. Novartis Pharmaceuticals Corp. Rev Jun 2018.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.
4. Ward MM, Deodhar A, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology*. 2015.
5. Van der Heijde D, Ramiro S, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Annals of the Rheumatic Diseases*. 2017;76:978-991

Non Formulary	
Brand Name	Generic Name
ARANESP	darbepoetin alfa
PROCRIT	epoetin alfa
EPOGEN	epoetin alfa

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 non-cardiac, 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. Trial and failure of at least 30 days of RETACRIT.

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

References

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Brand Name	Generic Name
DEMSER	metyrosine

CRITERIA FOR COVERAGE/NONCOVERAGE
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Demser (metyrosine) is a tyrosine hydroxylase inhibitor indicated in the treatment of pheochromocytoma.

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

1. The patient has a diagnosis of pheochromocytoma and the patient has a surgical resection planned, has a contraindication to surgery, or has malignant pheochromocytoma.
2. Prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the management of pheochromocytoma.
3. 12 years of age and older

Exclusion Criteria: Treatment of essential hypertension

Continuation Criteria: Positive response to therapy

Approval length: Initial and continuation approval for 6 months

Note: Request for brand Demser requires trial and failure of the generic product.

References:

1. Demser™ capsules [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; December 2017.
2. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.

Brand Name	Generic Name
DIFICID	fidaxomicin

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexasolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Covered products	Brand or generic Name
Donepezil tablets 5, 10 mg	ARICEPT
Donepezil orally disintegrating tablets 5, 10 mg	ARICEPT ODT
Donepezil tablets 23 mg	ARICEPT

CRITERIA FOR COVERAGE/NONCOVERAGE

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:

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:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu>. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: <http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/>. 9/9/17.
3. Aricept prescribing information. Woodcliff Lake, NJ. Eisai Inc. Rev Feb 2016.
4. Doody RS, Stevens JC, et al. Practice parameter: Management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. May 2001;Vol 56;no 9;1154-1166.
5. Folstein MF, Folstein SE, et al. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975;12:189-198. www.dementiatoday.com/wp-content/uploads/2012/06/MiniMentalStateExamination.pdf.

Brand Name	Generic Name
JANUVIA	sitagliptin
JANUMET / JANUMET XR	sitagliptin/metformin
TRADJENTA	linagliptin
JENTADUETO	linagliptin/metformin
KOMBIGLYZE XR	Saxagliptin/metformin
ONGLYZA	saxagliptin
TRIJARDY XR	

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 \geq 5.7% **and** FPG \geq 100 mg/dL and $<$ 126 mg/dL (7.0 mmol/L) OR HbA1c $<$ 5.7%).

References:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 10/2019.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 10/2019.
3. American Diabetes Association Standards of Medical Care in Diabetes – 2018. *Diabetes Care*. Jan 2019;42(Suppl. 1). Accessed at: https://care.diabetesjournals.org/content/42/Supplement_1. 10/2019.
4. AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm 2019. *Endocr Pract*. 2019. Accessed at: <https://www.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatment-algorithms/comprehensive.10/2019>.
5. Nauck MA, Kahle M, Baranov O. Addition of a dipeptidyl peptidase-4 inhibitor, sitagliptin, to ongoing therapy with the glucagon-like peptide-1 receptor agonist liraglutide: A randomized controlled trial in patients with type 2 diabetes. *Diabetes Obes Metab*. 2017 Feb; 19 (2):200-207. doi: 10.1111/dom.12802. Epub 2016 Nov 9.
6. European society of cardiology guidelines (ESC)/European association for the study of diabetes (EASD)-2019. *European Heart Journal*. Aug 31, 2019. Accessed at: <https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehz486/5556890>

NONFORMULARY	
Brand Name	Generic Name
Dupixent	dupilumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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

- Treatment of moderate to severe atopic dermatitis in adults and pediatric patients ≥6 years of age 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
- Treatment of Chronic Rhinosinusitis with Nasal Polyps in patients 18 years of age and older

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 or pediatric patient ≥6 years of age 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. One oral systemic therapy such as cyclosporine, methotrexate, azathioprine, or mycophenolate
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 in a patient 12 years or older. 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 OR member has required continuous use of oral corticosteroid therapy in the past 90 days.
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 in a patient 18 years of age or older.
 - i. Chronic sinusitis: 22-item sino-nasal outcome test (SNOT-22) score ≥ 50AND
 - 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 severity scores from baseline.
2. Decrease in affected body area from baseline by 50%.
3. 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:

1. Dupixent injection prescribing information. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Rev Oct 2018.
2. Eichenfield, LF, Tom WL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *Journal of the American Academy of Dermatology*. U.S. National Library of Medicine, Feb. 2014. Web. 23 Mar. 2017.
3. *Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2018.*

Brand Name	Generic Name
ELEPSIA XR	levetiracetam

CRITERIA FOR COVERAGE/NON-COVERAGE

Elepsia XR tablet is indicated for the treatment of focal (partial) onset seizures in adults and adolescents ≥ 12 years of age with epilepsy.

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

1. Member is 12 years of age or older; AND
2. Member is using as adjunctive treatment for the treatment of partial-onset seizures; AND
3. Member has tried and failed at least 2 preferred generic anticonvulsants, one of which should be generic Keppra XR tablet, unless contraindicated.

Quantity Level Limits:

1. For the following strengths: 1000mg/1500mg: QL is #60 every 30 days

Approval Length: Initial approval for 6 months to evaluate response, further approvals may be extended to 12 months dependent on clinical response.

Requests for Elepsia XR may not be approved for the following:

Moderate or severe renal impairment

References

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 6/2021
2. Facts& ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 6/2021

Brand Name	Generic Name
ELMIRON	pentosan polysulfate sodium

CRITERIA FOR COVERAGE/NON-COVERAGE

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:

1. Elmiron prescribing information. Titusville, NJ. Janssen Pharmaceuticals, Inc. Rev May 2018.
2. Hanno PM, Burks DA, Clemens JQ, et al. Diagnosis and treatment of interstitial cystitis/ bladder pain syndrome. American Urological Association. Updated 2014.
3. Clemens, J Q. Management of interstitial cystitis/bladder pain syndrome. UpToDate. Updated Jun 2018.
4. Parsons CL, Benson G, Childs SJ, et al. A quantitatively controlled method to study prospectively interstitial cystitis and demonstrate the efficacy of pentosan polysulfate. J Urol. 1993;150:845–848.

Nonformulary	
Brand Name	Generic Name
EMFLAZA	deflazacort

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 $\geq 10\%$ 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:

1. Emflaza prescribing information. Northbrook, IL. Marathon Pharmaceuticals. Rev Feb 2017.

NON FORMULARY	
Brand Name	Generic Name
EMSAM	selegiline transdermal

CRITERIA FOR COVERAGE/NONCOVERAGE
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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, paroxetine, 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. 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:

1. Emsam prescribing information. Morgantown, WV. Somerset Pharmaceuticals, Inc. Rev 7/2017.
2. Gelenberg AJ, Freeman MP. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. American Psychiatric Association. 2010.
3. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
4. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer.
5. Bodkin JA, Amsterdam JD. Transdermal selegiline in major depression: A double-blind, placebo-controlled, parallel-group study in outpatients. *Am J Psychiatry*. 2002;159(11):1869–1875.

Brand Name	Generic Name
ENTRESTO	sacubitril/valsartan

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. Diagnosis of heart failure and member meets one of the following:

- 18 years of age and older with New York Heart Association (NYHA) Class II-IV chronic heart failure with a reduced ejection fraction (HFrEF) of less than or equal to 40%
- 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction

3. For members 18 or older with heart failure and a reduced ejection fraction (HFrEF) of less than or equal to 40%:

- a. The member must have had a trial of an ACE inhibitor or ARB for at least 4 weeks
- b. Member is tolerating an angiotensin receptor blocker (ARB) or an angiotensin-converting enzyme inhibitor (ACEI) and Entresto will replace the angiotensin receptor blocker (ARB) and/or angiotensin-converting-enzyme inhibitor (ACEI).

4. c. Use in conjunction with other heart failure therapies (For example beta blockers, aldosterone antagonist, and combination therapy with hydralazine and isosorbide dinitrate) For members 1 year or older with symptomatic heart failure and systemic left ventricular systolic dysfunction:

- a. Member has tried and failed enalapril.

5. Member does not have severe hepatic impairment (Child Pugh Class C) or a history of angioedema with previous ACE inhibitor or ARB therapy

6. Member is not pregnant

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:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 06/2021.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 06/2021.
3. Yancy CW, Jessup M, et al. 2016 ACC/AHA/HFS A Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *Circulation*. 2016; 134:e282-e293
4. Entresto prescribing information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Rev 8/2015.
5. McMurray JJV, Packer M, Desai AS, et al. Baseline characteristics and treatment of patients in Prospective comparison of ARNI with ACEI to Determine Impact on Global Mortality and morbidity in Heart Failure trial (PARADIGM-HF). *Eur J Heart Fail*. 2014;16(7):817-825.

NON-FORMULARY	
Brand Name	Generic Name
EPIDIOLEX	Cannabidiol oral solution

CRITERIA FOR COVERAGE/NON-COVERAGE

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

- Member is 2 years of age or older.
- Prescribed by, or in consultation with a Neurologist.
- Member will be on a seizure medication while on Epidiolex
- Serum transaminases(ALT and AST) and bilirubin levels are taken prior to starting treatment

Lennox-Gastaut syndrome (LGS):

- Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)
- Member had trial and failure of, intolerance or contraindication to clobazam (generic Onfi) or Banzel AND TWO other formulary antiepileptic medications (Valproic acid, topiramate, lamotrigine, and/or felbamate).

Dravet syndrome (DS):

- Diagnosis of seizures associated with Dravet Syndrome (DS)
- Member had trial and failure of, intolerance or contraindication to at least two other formulary antiepileptic medications (valproic acid, topiramate, levetiracetam).
 - Note: carbamazepine and analogs (oxcarbazepine, Aptiom), lamotrigine, phenytoin may aggravate seizures and should be avoided in Dravet Syndrome treatment.

Initial approval duration: 6 months.

Continuation criteria:

- Member is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration)
- Provider continues monitoring Serum transaminases (ALT and AST) and bilirubin levels:
 - Serum transaminase level has not been greater than 3 times the upper limit of normal (ULN) while accompanied by bilirubin greater than 2 times the ULN
 - Serum transaminase level has not been sustained at greater than 5 times the ULN

Continuation approval duration: 12 months.

Dosing:

- Starting dose is 2.5mg/kg by mouth twice daily. After one week, the dose can be increased to 5mg/kg by mouth twice daily. The maximum recommended maintenance dose is 20mg/kg/day.

- Dosage adjustment is recommended for patients with moderate (Child-Pugh B) or severe hepatic impairment (Child-Pugh C).

References:

1. Product Information: EPIDIOLEX(R) oral solution, cannabidiol oral solution. Greenwich Biosciences Inc. (per FDA), Carlsbad, CA, 2018. Accessed May 2020.
2. Epidiolex. Micromedex solutions [database online]. Available at: <http://www.micromedexsolutions.com>. Accessed May 2020.
3. Wilfong A. Epilepsy Syndromes in Children. Waltham, MA: UpToDate. Last modified: Apr 2020. Accessed May, 2020.
4. Nascimento FA, Andrade DM. Dravet Syndrome: Management and Prognosis. Waltham, MA. UpToDate. Last modified Apr 2020. Accessed May, 2020.

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 $\leq 5 \times$ 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

1. Esbriet [prescribing information]. Brisbane, CA: InterMune Inc.; Accessed 11/2016
2. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
3. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Non Formulary	
Brand Name	Generic Name
EUCRISA	crisaborole

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).

Class	Drug	Dosage Form	Strength (%)
<i>Very High Potency</i>	augmented betamethasone dipropionate	Oint	0.05
	clobetasol propionate	Cream, oint	0.05
	diflorasone diacetate	Ointment	0.05
	halobetasol propionate	Cream, oint	0.05
<i>High Potency</i>	amcinonide	Oint	0.1
	augmented betamethasone dipropionate	Cream	0.05
	betamethasone dipropionate	Cream, foam, oint, soln	0.05
	desoximetasone	Oint	0.25
	fluocinonide	Cream, gel, oint, soln	0.05
	halocinonide	Cream, oint	0.1
	mometasone furoate	Oint	0.1
	triamcinolone acetonide	Cream, oint	0.5
<i>Medium Potency</i>	betamethasone valerate	Cream, lotion, oint	0.1
	desoximetasone	Cream	0.05
	fluocinolone acetonide	Oint	0.025
	flurandrenolide	Cream, oint	0.05

	fluticasone propionate	Cream	0.05
	fluticasone propionate	Oint	0.005
	mometasone furoate	Cream, oint, soln	0.1
	triamcinolone acetonide	Cream, oint	0.1
<i>Lower medium potency</i>	hydrocortisone butyrate	Oint	0.1
	hydrocortisone probutate	Cream	0.1
	hydrocortisone valerate	Oint	0.1
<i>Low potency</i>	alclometasone dipropionate	Oint	0.05
	desonide	Cream, gel, foam, oint	0.05
	fluocinolone acetonide	Cream, soln	0.01

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:

1. Eucrisa prescribing information. New York, NY. Pfizer Labs, Inc. Rev Oct 2017.
1. Paller, AS, Tom WL, et al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. Journal of the American Academy of Dermatology. 2016 Sep;75(3):494-503
2. LF Tom, WL Berger, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. Journal of the American Academy of Dermatology. 2014 Jul;71(1):116-32.

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

Brand Name	Generic Name
EURAX	Crotamiton
SKLICE	ivermectin
Natroba	Spinosad

CRITERIA FOR COVERAGE/NONCOVERAGE

Diagnosis of scabies infestation:

Eurax/crotamiton and Spinosad topical suspension 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).
- Spinosad: Age 4 years and older
- Eurax: Age 18 years and older
- If request is for Brand Natroba topical suspension, trial and failure of the generic Natroba topical suspension must be tried first, unless contraindicated.
-

Diagnosis of head lice infestation:

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
- If request is for Brand Sklice topical lotion, trial and failure of the generic Sklice topical lotion AND Spinosad topical suspension must be tried first, unless contraindicated.

Member must meet following for continuation of coverage:

- Member has developed a recurrent infestation.

Re-authorization duration: 1 month.

References:

1. Micromdex/Drugdex at www.microdexsolutions.com. Accessed 02/2019.
2. CDC-Lice treatment: <https://www.cdc.gov/parasites/lice/head/treatment.html>. Accessed 02/2019.
3. CDC-Scabies-treatment: <https://www.cdc.gov/parasites/scabies/treatment.html>. Accessed 02/2019.

Brand Name	Generic Name
EVRYSDI	risdiplam

CRITERIA FOR COVERAGE/NON-COVERAGE

EVRYSDI is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older. Evrysdi is available as an oral solution that is administered once a day.

EVRYSDI will be considered for coverage under the **Pharmacy** benefit program and considered medically necessary for the treatment of **Types I, II, or III** spinal muscular atrophy (SMA) when the following criteria are met. (*internal note: Type IV was not studied*)

A. **Initiation** of therapy requires all of the following criteria to be met:

1. Documentation of SMA type 1, 2, or 3 diagnosis and is prescribed by a pediatric neurologist with SMA treatment expertise.
2. Member is at least 2 months of age or older.
3. Clinical lab documentation of one of the following:
 - a. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)
 - b. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
3. Documentation of genetic testing confirming presence of at least two copies of SMN2. (*Internal note: Per the Evrysdi clinical FDA trials every patient had at least 2 copies of SMN2 in order to enroll in trial. SMN2 presence is required in order to make SMN1 genes. SMN1 gene is the one that is deficient and causes SMA. SMN2 gene helps produce more SMN1 gene by use of Evrysdi, so SMN2 gene needs to be present. Not every patient has two SMN2 genes present.*)
4. Exam results submitted of at least **one** of the following to establish baseline motor ability:
 - a. **Bayley Scales of Infant and Toddler Development – Third Edition (BSID-III)** gross motor scale and with ability to sit without support for at least 5 seconds per Item 22.
 - b. **Motor Function measure 32 (MFM32) score**
 - c. **Revised Upper Limb Module (RULM) score**
(*Internal note: Source FDA studies*)
5. Member is not dependent on either invasive ventilation or tracheostomy, or noninvasive ventilation for ≥ 16 hours per day. (*Internal note: Source- the Evrysdi clinical studies*)
6. Dosing is done in accordance with the FDA approved labeling per current weight at time of request. Maximum approvable dose and dosing of 5mg daily once weight reaches 20 kg.
8. No documented previous use of onasemnogene abeparvovec-xioi (Zolgensma). (*Internal note: Considered experimental at this time if previous use of Zolgensma.*)

Initial and Continuation Approval Duration: 6 months

B. **Continuation** after initiation of therapy, and every 6 months thereafter, requires all of the below to be met:

1. Treatment continues to be prescribed by a pediatric neurologist with SMA treatment expertise and all initial criteria continues to be met.

2. No respiratory dependency on any of the below:
 - a. Invasive ventilation or tracheostomy
 - b. Non-invasive ventilation for a period ≥ 6 hours per day
 - c. Permanent ventilation (≥ 16 hours ventilation/day continuously for > 21 days in absence of an acute reversible event or tracheostomy)
3. Clinical documentation supports positive therapeutic response to Evrysdi, from pretreatment baseline, as demonstrated by any of the following. Evaluation must occur ≤ 1 month prior to renewal request and must be done consistent with the baseline scale/test used for initial approval.
 - a. **Bayley Scales of Infant and Toddler Development – Third Edition (BSID-III)**
 - i. Documentation of ability to sit independently for ≥ 5 seconds, per item 22.
 - b. **Motor Function measure 32 (MFM32) score**
 - i. Documentation of 3 point or greater change from baseline
 - c. **Revised Upper Limb Module (RULM) score**
 - i. Documentation of increase in total score from baseline

(Internal note: Goal is to not regress in score so no improvement from baseline for a. is acceptable but a positive initial response must be seen with b. and c. and then can stabilize.)

References:

1. Evrysdi prescribing information. South San Francisco, CA. Genentech, Inc. Rev Aug 2020.
www.gene.com/download/pdf/evrysdi_prescribing.pdf
2. Bodamer OA. Spinal muscular atrophy. UpToDate, Inc. Waltham, MA. Accessed Sep 10, 2020. Rev May 2020.
3. Finkel RS, Mercuri E, et al. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics. *Neuromuscul Disord.* 28(2018);197-207.
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Brand Name	Generic Name
JADENU/EXJADE	Deferasirox

CRITERIA FOR COVERAGE/NONCOVERAGE

Exjade® (deferiasirox) and Jadenu® (deferiasirox) are iron chelating agents indicated for:

- The treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older.
- Treatment of chronic iron overload in patients ≥10 years of age with non-transfusion-dependent thalassemia syndromes and with a liver iron concentration of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dry weight) and a serum ferritin >300 mcg/L.

Generic Jadenu and generic Exjade will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Diagnosis of chronic iron overload due to blood transfusions (transfusional iron overload)

1. Age 2 years and older
2. Pretreatment serum ferritin level is consistently greater than 1000 mcg/L.
3. Renal function has been evaluated (eGFR greater than 60 ml/min)
4. Dose of generic Exjade will not exceed 40 mg/kg, dose of generic Jadenu will not exceed 28 mg/kg.

Continuation Criteria: Positive response to therapy (decrease in serum ferritin levels compared to baseline) and serum ferritin is not below 500 mcg/L.

Approval length: Initial and continuation approval for 6 months

Note: Request for brand Exjade or Jadenu requires trial and failure of the generic product.

Diagnosis of chronic iron overload with non-transfusion dependent thalassemia

1. Age 10 years and older
2. Pretreatment serum ferritin level is greater than 300 mcg/L.
3. Pretreatment liver iron concentration (LIC) is at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).
4. Dose of generic Exjade will not exceed 20 mg/kg (round to nearest increment of 500mg tablet when possible), dose of generic Jadenu will not exceed 14 mg/kg.

Continuation Criteria: Positive response to therapy (decrease in serum ferritin levels compared to baseline) and serum ferritin is not below 300 mcg/L.

Approval length: Initial and continuation approval for 6 months

Note: Request for brand Exjade or Jadenu requires trial and failure of the generic product.

References:

1. Exjade [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019.
2. Jadenu [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019.

HCA Regulatory Exclusions	
EXCLUDED DRUGS	

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. Medical Marijuana.
6. Non-FDA approved drugs – Drugs that are not approved by the FDA. This includes drugs not assigned a National Drug Code (NDC).
7. Experimental Medications
8. 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:

1. AHCCCS Medical Policy Manual. Policy 310-V Prescription medications/Pharmacy Services. Rev July 2019.
2. Arizona Administrative Code (AAC). Arizona Health Care Cost Containment System – Administration. Title 9, Chapter 22. Rev Jun 2017.
3. Social Security Act. Payment for Covered Outpatient Drugs. Title XIX §1927(d)(2).

Covered products	Brand or generic Name
Ezetimibe	ZETIA

CRITERIA FOR COVERAGE/NONCOVERAGE

Ezetimibe will be considered for coverage when the following criteria are met:

- Thirty (30) day fill of a statin in the previous 90 days

Approval duration: 12 months

References:

1. Grundy SM, et al. 2018 ACC/AHA Guideline for the Treatment of Blood cholesterol: A report of the ACC/AHA taskforce on practice guideline. Available at:
<https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000625>
2. Zetia Prescribing Information. Merck/Schering-Plough Pharmaceuticals, Whitehouse Station. NJ 0889. February 2019.
3. Clinical Pharmacology. Tampa, FL: Gold Standard, Inc.; 2019. URL: <http://clinicalpharmacology-ip.com>.

Covered Product	Brand Name
febuxostat	ULORIC

CRITERIA FOR COVERAGE/NON-COVERAGE

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 reactions
 - 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 less than 6 mg/dL while adherent to Uloric per prescription claim history and documentation of a reduced frequency of gout attacks.

References:

1. Uloric prescribing information. Deerfield, IL. Takeda Pharmaceuticals America, Inc. Rev Feb 2018.

2. Khanna D, Fitzgerald JD, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 1: Systematic Nonpharmacologic and Pharmacologic Therapeutic Approaches to Hyperuricemia. *Arthritis Care & Research*. 2012; 64(10): 1431-1446).

Brand Name	Generic Name
FEMRING	estradiol vaginal ring

CRITERIA FOR COVERAGE/NONCOVERAGE
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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), Yuvaferm (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.

Non-Formulary Chelating Agent - Brand Name
FERRIPROX- non-formulary (deferiprone)

CRITERIA FOR COVERAGE/NONCOVERAGE
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Ferriprox® (deferiprone) is an iron chelating agents indicated for:

- The treatment of patients with transfusional iron overload due to thalassemia syndromes or due to sickle cell disease or other anemias.

Note- If request is for Brand Ferriprox 500mg tablet, member must have an adequate trial and failure of generic Ferriprox (deferiprone) first, or contraindication.

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

I. Initial Approval Criteria

1. Diagnosis of transfusional iron overload due to thalassemia syndromes or due to sickle cell disease or other anemias;
2. Age ≥ 8 years (tablets) or ≥ 3 years of age (oral solution);
3. Transfusion history of ≥ 100 mL/kg of packed red blood cells (e.g., ≥ 20 units of packed red blood cells for a 40 kg person) and a serum ferritin level $> 1,000$ mcg/L;
4. Dose does not exceed 99 mg/kg per day.
5. Failure of deferasirox tablets (Exjade, Jadenu) [PA required], unless clinically significant adverse effects are experienced or all are contraindicated.

II. Continued Therapy

1. Currently receiving medication via pharmacy claims history;
2. Current documentation (within the past 30 days) shows serum ferritin level ≥ 500 mcg/L;
3. If request is for a dose increase, new dose does not exceed 99 mg/kg per day.

Approval length: Initial and continuation approval for 6 months

Dosing Regimen (available as oral solution or oral tablet):

75 mg/kg PO in 2 or 3 divided doses for a total daily dose of 75 to 99 mg/kg/day in 2 or 3 divided doses

Quantity Limit:

99mg/kg/day

References:

1. Ferriprox Tablets Prescribing Information. Rockville, MD: ApoPharma USA, Inc.; May 2020. Available at www.ferriprox.com. Accessed May 21, 2021.
2. Ferriprox Oral Solution Prescribing Information. Rockville, MD: ApoPharma USA, Inc.; May 2017. Available at http://www.ferriprox.com/us/pdf/ferriprox_full_pi.pdf. Accessed May 21, 2021.
3. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. *Acta Haematol.* 2013; 130: 64-73. DOI: 10.1159/000345734.
4. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. *Blood.* November 1, 2012; 120(18): 3657-3669.
5. Maggio A, Vitranò A, Capra M, et al. Long-term sequential deferiprone-deferoxamine versus deferiprone alone for thalassaemia major patients: a randomized clinical trial. *Br J Haematol.* 2009;145:245-54.

Brand Name	Generic Name
FORTEO – PA REQ	teriparatide
TYMLOS – Non formulary	abaloparatide

CRITERIA FOR COVERAGE/NON-COVERAGE

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 $\geq 3\%$ or a 10-year probability of a major osteoporosis-related fracture $\geq 20\%$ 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 $\geq 3\%$ or a 10-year probability of a major osteoporosis-related fracture $\geq 20\%$ 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. The member has a documented trial and failure of Forteo.
 9. 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:

1. Cosman F, deBeur SJ, et al. Clinician's Guide to Prevention and Treatment of Osteoporosis. *Osteoporosis Int.* 25(8) Jun 2014.
2. Watts NB, Adler RA, et al. Endocrine Society et al (2012) Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 97(6):1802–1822.
3. Camacho PM, Petak SM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2016. *Endocr Pract.* 2016;22(Suppl 4).
4. Forteo prescribing information. Indianapolis, IN. Eli Lilly and Co. Rev Oct 2016.
5. Tymlos prescribing information. Waltham, MA. Radium Health, Inc. Rev Apr 2017.

Criteria Name

Continuous Glucose Monitor – Freestyle Libre, DexCom
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CRITERIA FOR COVERAGE/NONCOVERAGE

FreeStyle Libre and DexCom 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 with diabetes. The original FreeStyle Libre does not alarm for hypoglycemia or hyperglycemia whereas Dexcom G6 and Freestyle Libre 2 do have alarms. Fingerstick glucose levels are required to confirm hypoglycemia.

***Note: Original **Freestyle Libre** is approved for use in patients **18 and older**. **FreeStyle Libre 2** is approved for use in patients **4 years and older**. **Dexcom** may be used in patients **2 and older**.

FreeStyle Libre and FreeStyle Libre 2 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 has been using a blood glucose monitor (BGM) and performing frequent (four or more times a day) testing; and
- c. The member is insulin-treated with multiple (three or more) daily injections of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and
- d. The member's insulin treatment regimen requires frequent adjustment by the member on the basis of BGM or CGM testing results; and
- e. The member does not have episodes of hypoglycemic unawareness or nocturnal hypoglycemia as evidenced by two episodes over a two week period. (only applies to **FreeStyle Libre**)
 - i. *Note: FreeStyle Libre PI states "The FreeStyle Libre system has not been evaluated for use in patients with hypoglycemic unawareness and will not automatically alert you of a hypoglycemic event." FreeStyle Libre is not appropriate for use in most patients with hypoglycemic unawareness. When there is a medically necessary reason to have high and low alerts as a feature of the CGM, coverage of FreeStyle Libre 2 is appropriate over FreeStyle Libre. DexCom is appropriate if FreeStyle Libre 2 is contraindicated for the member.*

DexCom will be considered for coverage when the following criteria are met:

- a. All of the above, plus
- b. FreeStyle Libre (preferred product) is contraindicated in the member

Limitations and Exclusions:

1. FreeStyle Libre readers and sensors must be dispensed through an in-network pharmacy.
 - o Requests for coverage through a DME vendor must be redirected to an in-network pharmacy.
2. Quantity Limit:
 - o Freestyle: 2 per 28 days
 - o Dexcom: 3 per 30 days

Approval Duration: 12 months

Approval Duration: 12 months

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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

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:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu>. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: <http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/>. 9/9/17.
3. Razadyne prescribing information. Titusville NJ. Janssen Pharmaceuticals. Rev Sep 2016.
4. Doody RS, Stevens JC, et al. Practice parameter: Management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. May 2001;Vol 56;no 9;1154-1166.
5. Folstein MF, Folstein SE, et al. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-198. www.dementiatoday.com/wp-content/uploads/2012/06/MiniMentalStateExamination.pdf.

Brand Name	Generic Name
BYETTA PEN	exenatide
BYDUREON PEN/VIALS (D/C'd March 2021)	exenatide
VICTOZA PEN	liraglutide
SYMLIN PEN	pramlintide acetate
TRULICITY PEN	

CRITERIA FOR COVERAGE/NONCOVERAGE

Bydureon Pens were d/c'd by the manufacturer March 2021. Bydureon BCISE is NONFORMULARY

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 (90days) 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:

- Pre-diabetic patients (e.g., HbA1c \geq 5.7% **and** FPG \geq 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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 10/2019
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 10/2019
3. American Diabetes Association Standards of Medical Care in Diabetes – 2018. *Diabetes Care*. Jan 2019;42 (Suppl. 1). Accessed at: https://care.diabetesjournals.org/content/42/Supplement_1. 10/2019.
4. AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm 2019. *Endocr Pract*. 2019. Accessed at: <https://www.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatment-algorithms/comprehensive>. 10/2019.
5. Symlin/SymlinPen [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; February 2019.
6. Nauck MA, Kahle M, Baranov O. Addition of a dipeptidyl peptidase-4 inhibitor, sitagliptin, to ongoing therapy with the glucagon-like peptide-1 receptor agonist liraglutide: A randomized controlled trial in patients with type 2 diabetes. *Diabetes Obes Metab*. 2017 Feb; 19 (2):200-207. doi: 10.1111/dom.12802. Epub 2016 Nov 9.
7. European society of cardiology guidelines (ESC)/European association for the study of diabetes (EASD)-2019. *European Heart Journal*. Aug 31, 2019. Accessed at: <https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehz486/5556890>
8. Busch RS, Kane MP. Combination SGLT2 inhibitor and GLP-1 receptor agonist therapy: a complementary approach to the treatment of type 2 diabetes. *Postgrad Med*. 2017 Sep; 129 (7):686-697. doi: 10.1080/00325481.2017.1342509. Epub 2017 Jun 28
9. DeFronzo RA. Combination therapy with GLP-1 receptor agonist and SGLT2 inhibitor. *Diabetes Obes Metab*. 2017 Oct; 19(10):1353-1362. doi: 10.1111/dom.12982. Epub 2017 Jun 7.

Glucagon Agents – NON FORMULARY
Gvoke Hypopen/PFS
Baqsimi

CRITERIA FOR COVERAGE/NON-COVERAGE

Gvoke is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. Gvoke is available as an auto-injector and prefilled syringe for subcutaneous administration.

Baqsimi is an intranasal antihypoglycemic agent indicated for the treatment of severe hypoglycemia in adult and pediatric patients with diabetes ages 4 years and above..

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

- Patient must be at least 2 years old AND
- Patient has a diagnosis of type 1 or type 2 diabetes AND
- Patient must NOT have pheochromocytoma, an insulinoma, or known hypersensitivity to glucagon or any of the excipients in the product AND
- Patient has a documented trial and failure of, or contraindication to, use of Glucagon kit AND
- Prescriber provides documentation to substantiate ALL the following:
 - Patient and/or caregiver has been trained to recognize the signs and symptoms of hypoglycemia and has a plan of action to reverse hypoglycemia when it occurs AND
 - Patient and/or caregiver has been instructed on how to use Gvoke and how to discard and replace used or unused Gvoke AND
 - Patient has a comprehensive diabetes care plan including self-monitoring of blood glucose or continuous glucose monitoring

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

- Patient must be at least 4 years old AND
- Patient has a diagnosis of type 1 or type 2 diabetes AND
- Patient must NOT have pheochromocytoma, an insulinoma, or known hypersensitivity to glucagon or any of the excipients in the product AND
- Patient has a documented trial and failure of, or contraindication to, use of Glucagon kit AND
- Prescriber provides documentation to substantiate ALL the following:
 - Patient and/or caregiver has been trained to recognize the signs and symptoms of hypoglycemia and has a plan of action to reverse hypoglycemia when it occurs AND
 - Patient has been instructed on how to use Baqsimi and how to discard and replace used or unused Baqsimi AND

- Patient has a comprehensive diabetes care plan including self-monitoring of blood glucose or continuous glucose monitoring

Quantity Limits:

- Baqsimi: 2 devices per 30 days
- Gvoke: 2 autoinjectors or 2 prefilled syringes per 30 days

References:

1. Gvoke prescribing information https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212097s008lbl.pdf As accessed 7/2021 (last update: 7/15/2021)
2. Baqsimi prescribing information https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210134s002lbl.pdf As accessed 7/2021
3. American Diabetes Association Standards of Medical Care in Diabetes – 2018. *Diabetes Care*. Jan 2019;42 (Suppl. 1). Accessed at: https://care.diabetesjournals.org/content/42/Supplement_1. 7/2021.

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 \geq 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 \geq 5.7% **and** FPG \geq 100 mg/dL and $<$ 126 mg/dL (7.0 mmol/L) OR HbA1c $<$ 5.7%).

References:

4. Glyxambi prescribing information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. Rev Dec 2017.
5. American Diabetes Association Standards of Medical Care in Diabetes – 2018. *Diabetes Care*. Jan 2019;42 (Suppl. 1). Accessed at: https://care.diabetesjournals.org/content/42/Supplement_1. 10/2019.
6. AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm 2019. *Endocr Pract*. 2019. Accessed at: https://www.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatment-algorithms/comprehensive_10/2019.
7. European society of cardiology guidelines (ESC)/European association for the study of diabetes (EASD)-2019. *European Heart Journal*. Aug 31, 2019. Accessed at: <https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehz486/5556890>

Non-Formulary- Brand Name

Amantadine ER (Gocovri capsule, Osmolex ER tablet)
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CRITERIA FOR COVERAGE/NONCOVERAGE
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Amantadine extended-release (Gocovri, Osmolex ER) is a weak uncompetitive antagonist of the N-methyl-D-aspartate (NMDA) receptor and is indicated for:

- Gocovri: for the treatment of dyskinesia in patients with Parkinson's disease (PD) receiving levodopa-based therapy, with or without concomitant dopaminergic medications; AND as adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes.
- Osmolex ER: for the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients.

Gocovri and Osmolex ER will be considered for coverage under the pharmacy benefit program when the following criteria are met:

Dyskinesia in Patients with Parkinson's Disease (must meet all):

1. Diagnosis of dyskinesia in patients with PD;
2. Age \geq 18 years;
3. Member is receiving levodopa-based therapy;
4. Member must use immediate-release amantadine, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for Gocovri, member must first use Osmolex ER (PA required), unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 274 mg (2 capsules) per day for Gocovri or 322mg (1 tablet of 129mg and 1 tablet of 193mg) per day for Osmolex ER.

Parkinson's Disease With "Off" Episodes (must meet all):

1. Diagnosis of PD;
2. Request is for Gocovri;
3. Age \geq 18 years;
4. Member is experiencing "off" time (see Appendix D) on levodopa/carbidopa therapy;
5. Failure of two of the following adjunct drugs prescribed in combination with levodopa/carbidopa, each from different classes, unless contraindicated or clinically significant adverse effects are experienced:
 - a. MAO-B inhibitor: rasagiline;
 - b. COMT inhibitor: entacapone (Comtan®/Stalevo®)
 - c. Dopamine agonist; ropinirole/ropinirole ER, pramipexole/pramipexole ER

Note- prior authorization may be required for the above agents

6. Member must use immediate-release amantadine, unless contraindicated or clinically significant adverse effects are experienced;
7. Prescribed in combination with levodopa/carbidopa;
8. Dose does not exceed 274mg (2 capsules) per day.

Drug-Induced Extrapyramidal Reactions (must meet all):

1. Diagnosis of a drug-induced extrapyramidal reaction;
2. Request is for Osmolex ER;
3. Age \geq 18 years;
4. Member must use immediate-release amantadine, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 322mg per day (1 tablet of 129mg and 1 tablet of 193mg).

Length of approval for initial and renewal: 12 months

Dosing:

Drug Name	Indication	Dosing	Maximum Dose
Amantadine ER (Gocovri)	Dyskinesia or “off” episodes in Parkinson’s disease	137 mg PO QHS for 1 week. After 1 week, increase to 274 mg (two 137 mg capsules) PO QHS	274 mg/day
Amantadine ER (Osmolex ER)	Dyskinesia in Parkinson’s disease; drug induced extrapyramidal reaction	129 mg PO QAM, increase dose in weekly intervals	322 mg/day

References:

1. Gocovri Prescribing Information. Emeryville, CA: Adamas Pharma, LLC; January 2021. Available at: https://www.gocovri.com/pdf/Gocovri_Prescribing_Information.pdf. Accessed May 21, 2021.
2. Oertel W, Eggert Karla, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson’s disease (EASE LID 3). Mov Disord. 2017 August 21. Available at: Doi: 10.1002/mds.27131.

Covered products	Brand or generic Name
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:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu>. Accessed 03/2019.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: <http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/>. 03/2019.
3. Gralise prescribing information. Newark, CA. Depomed, Inc. Rev July 2015.
4. Dubinsky RM, Kabbani H, et al. Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* Sept 2004 vol. 63 no. 6;959-965.
5. Johnson RW, Rice A, et al. Postherpetic Neuralgia. *N Engl J Med*. 2014;371:1526-33.
6. Bell, Amanda, Fashner, Julia. Herpes Zoster and Postherpetic neuralgia: Prevention and Management. *Am Fam Physician*. 2011 Jun 15; 83(12):1432-1437. <https://www.aafp.org/afp/2011/0615/p1432.html#sec-5>. Accessed on 02/2019.

Criteria Name
Growth Hormone (somatropin)

Preferred products	Non-Preferred Products
GENOTROPIN	HUMATROPE
NORDITROPIN	NUTROPIN AQ NUSPIN
	OMNITROPE
	ZOMACTIN
	ZORBTIVE
	SEROSTIM

CRITERIA FOR COVERAGE/NONCOVERAGE

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:

Test	Peak GH	BMI
ITT	≤5 ng/ml	N/A
Arginine	≤0.4	N/A
Glucagon	≤3 ng/ml	N/A
Arginine+ GHRH	≤11ng/m	<25 kg/m ²
	≤8 ng/ml	≥25 and <30 kg/m ²
	≤4 ng/ml	≥30kg/m ²
 - 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 hypothalamus 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

ZORBTIVE 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 $\geq 10\%$ 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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Formulary	
Brand Name	Generic Name
HEMLIBRA	emicizumab-kxwh

CRITERIA FOR COVERAGE/NON-COVERAGE

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 Hemophila 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:

1. Hemlibra prescribing information. South San Francisco, CA. Genentech, Inc. Oct 2018..
2. ICER. Institute for Clinical and Economic Review posts draft scoping document to guide review of emicizumab for hemophilia A.
3. Oldenburg J, Mahlangu JN, Kim B, et al. Emicizumab prophylaxis in hemophilia A with inhibitors. New Engl J Med. 2017;377(9):809-818.

Covered Product	Brand name
entecavir tablets, solution	BARACLUDE
adefovir dipivoxil tablets	HEPSERA

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:

1. Lok A, et al. Hepatitis B virus: Overview of management. Waltham, MA. UpToDate, Inc. Rev Sept 2017.
2. Terrault NA, Lok A, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. 2018;67;4:1560-1599.
3. Baraclude prescribing information. Princeton, NJ. Bristol-Myers Squibb Company. Rev Jun 2018.
4. Hepsera prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev Nov 2012.

Covered Product	Brand/Generic Name
MAVYRET	Glecaprevir + Pibrentasvir
Sofosbuvir/Velpatasvir	EPCLUSA

CRITERIA FOR COVERAGE/NON-COVERAGE

*** Sofosbuvir/Velpatasvir approvals must be placed at NDC level***

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.

Sofosbuvir/Velpatasvir is a fixed-dose combination of Sofosbuvir, a hepatitis C virus (HCV) NS5B polymerase inhibitor, and Velpatasvir, 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, with compensated cirrhosis (Child-Pugh A), or with decompensated cirrhosis when used in combination with Ribavirin.

Sofosbuvir/Velpatasvir also has an orphan drug designation for treatment of pediatric HCV infection.

Sofosbuvir/Velpatasvir is available in a tablet form and the recommended dose is one tablet taken once daily with food.

Approvable Treatment Regimens and Durations:

Mavyret:

Treatment Naïve or PRS experienced*	Treatment Duration	
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1, 2, 3, 4, 5, or 6	8 weeks	12 weeks

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

Mavyret:

Treatment Experienced	Previously treated with:	Treatment Duration	
Genotype	Regimen	No Cirrhosis	Compensated cirrhosis (CP-A)
1	NS5A inhibitor without NS3/4A	16 weeks	16 weeks
1	NS3/4A PI without NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5 or 6	PRS*	8 weeks	12 weeks
3	PRS*	16 weeks	16 weeks

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

NS5A inhibitors include: ledipasvir, sofosbuvir, daclatasvir

NS3/4A protease inhibitors include: simeprevir, boceprevir, telaprevir

Sofosbuvir/Velpatasvir:

Treatment Naïve or PRS experienced*	Treatment Duration		
	<i>Cirrhosis/Compensated Cirrhosis (Child-Pugh A)</i>	<i>Decompensated Cirrhosis (with Ribavirin)</i>	<i>Decompensated Cirrhosis (Ribavirin ineligible)</i>
1, 2, 3, 4, 5, or 6	12 weeks	12 weeks	24 weeks

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

Mavyret or Sofosbuvir/Velpatasvir 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.

AND

2. Age of the member is FDA approved for the product/dose

AND

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 which includes:
 - a. HCV genotype
 - b. Viral resistance status (when applicable)
 - c. Hepatic status (Child Pugh score)
 - d. HCV viral load

AND

4. Documentation submitted of:
 1. Prescribing provider assessment of member's ability to adhere to the treatment plan and documentation of this assessment within the clinical record. For members that would benefit from adherence aids, the treating provider shall refer the member to a treatment adherence program.
 2. Member agrees to adhere to the proposed course of treatment, including taking medications as prescribed, attending follow-up appointments, and, if applicable, participating in a treatment adherence program..

AND

5. 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).

AND

6. 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

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

AND

8. 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

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's ability to adhere to the planned course of retreatment has been assessed by the treating provider and documented within the clinical record..

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

- a. The retreatment is considered an experimental service as specified in A.A.C. R9-22-203.
- 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. Members who do not agree to adhere to the proposed course of treatment, including participating in a treatment adherence program if applicable.
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. Lost or stolen medication absent of good cause.
7. Fraudulent use of HCV medications.

Nonformulary	
Non-Formulary Hepatitis C treatments	

CRITERIA FOR COVERAGE/NON-COVERAGE

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. **All criteria for formulary Hepatitis C coverage (initial and/or retreatment) is met**, including 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

5. 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

Exclusions:

1. DAA dosages greater than the FDA approved maximum dosage.
2. Members who do not agree to adhere to the proposed course of treatment, including participating in a treatment adherence program if applicable.
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. Lost or stolen medication absent of good cause.
7. 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

*****Note, effective 10/1/2019, generic Epclusa is a preferred formulary product.**

Treatment naïve or treatment experienced with no cirrhosis or compensated cirrhosis

Approvable regimens in order of preferred status	Treatment naïve	Treatment experienced to interferon/ribavirin	Treatment experienced to PI**	Treatment experienced to NS5A***	Treatment experienced to sofosbuvir
Genotype 1	<i>Zepatier</i>	<i>Zepatier ± ribavirin</i>	<i>Zepatier/ribavirin</i>	<i>Vosevi</i>	<i>Vosevi</i>
	<i>Harvoni x 8wks*</i>	<i>Viekira XR</i>	<i>Epclusa</i>		
	<i>Epclusa</i>	<i>Epclusa</i>	<i>Harvoni/ribavirin</i>		
	<i>Viekira</i>	<i>Harvoni ± ribavirin</i>			
Genotype 2	<i>Epclusa</i>	<i>Epclusa</i>	<i>N/A</i>	<i>Vosevi</i>	-
Genotype 3	<i>Epclusa</i>	<i>Epclusa</i>	<i>N/A</i>	<i>Vosevi</i>	<i>Vosevi</i>
Genotype 4	<i>Zepatier</i>	<i>Zepatier</i>	<i>N/A</i>	<i>Vosevi</i>	-
	<i>Epclusa</i>	<i>Epclusa</i>			
	<i>Harvoni</i>	<i>Harvoni</i>			
Genotype 5 or 6	<i>Epclusa</i>	<i>Epclusa</i>	<i>N/A</i>	<i>Vosevi</i>	-

*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)

Approvable regimens in order of preferred status	Treatment naïve or treatment experienced
Genotype 1	<i>Epclusa/ribavirin</i>
	<i>Harvoni/ribavirin</i>
Genotype 2	<i>Epclusa/ribavirin</i>
Genotype 3	<i>Epclusa/ribavirin</i>
Genotype 4	<i>Epclusa/ribavirin</i>
Genotype 5 or 6	<i>Epclusa/ribavirin</i>

Liver transplant recipients

Approvable regimens in order of preferred status	Treatment naïve or treatment experienced
Genotype 1	<i>Viekira XR/ribavirin*</i>
	<i>Harvoni/ribavirin</i>
Genotype 2	-
Genotype 3	<i>Sovaldi/Daklinza/ribavirin</i>
Genotype 4	<i>Epclusa/ribavirin</i>
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)

Approvable regimens in order of preferred status	No cirrhosis	Compensated cirrhosis (Child-Pugh < 7)	Compensated cirrhosis (Child-Pugh < 7) and treatment experienced
Genotype 1	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 24 weeks</i>
Genotype 4	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 12 weeks</i>
Genotype 5	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 12 weeks</i>
Genotype 6	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 12 weeks</i>	<i>Harvoni x 12 weeks</i>

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

Approvable regimens in order of preferred status	No cirrhosis	Compensated cirrhosis (Child-Pugh < 7)	Compensated cirrhosis (Child-Pugh < 7) and treatment experienced
Genotype 1	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 12 weeks</i>
Genotype 2	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 12 weeks</i>
Genotype 3	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 16 weeks</i>

Genotype 4	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 12 weeks</i>
Genotype 5	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 12 weeks</i>
Genotype 6	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 8 weeks</i>	<i>Mavyret x 12 weeks</i>

Brand Name	Generic Name
HETLIOZ and HETLIOZ LQ	tasimelteon

CRITERIA FOR COVERAGE/NON-COVERAGE

HetlioZ is indicated for treatment of:

- Non-24-hour sleep-wake disorder (non-24) in adults
- Nighttime sleep disturbances in Smith-Magenis syndrome (SMS) in patients 16 years of age and older

HetlioZ LQ is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 to 15 years of age.

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

I. Initial approval criteria:

A. Non-24-Hour Sleep-Wake Disorder (must meet all):

1. Diagnosis of non-24 hour sleep-wake disorder.
2. Request is for HetlioZ capsules.
3. Age \geq 18 years.
4. 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).
5. 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.
6. Documentation the member is totally blind with no perception of light.
6. 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.
7. 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.
8. Dose does not exceed 20mg (1 capsule) per day.

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

B. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) (must meet all):

1. Diagnosis of SMS confirmed by genetic testing (confirmation of deletion 17p11.2 or *RAI1* mutation).
2. Request is for the treatment of nighttime sleep disturbances.
3. 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).
4. 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.
5. 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.
6. One of the following (a or b)
 - a. The request is for Hetlioz capsules AND the member is 16 years of age or older,
 - b. The request is for the Hetlioz LQ oral suspension AND the member is 3 to 15 years of age.
7. Dose does not exceed one of the following (a or b):
 - a. Hetlioz: 20 mg (1 capsule) per day;
 - b. Hetlioz LQ: 0.7 mg per kg per day if weight \leq 28 kg, 20 mg per day if weight $>$ 28 kg.

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

Quantity Limit:

20mg capsules: Thirty capsules per 30 days (MDD= 1)

4mg/ml oral suspension: 20mg once daily (MDD= 5ml)

Continuation Criteria:

1. Documentation the member has achieved adequate results with Hetlioz therapy according to the prescribing physician.
2. 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.
3. If request is for a dose increase, new dose does not exceed one of the following (a or b): a. Hetlioz: 20 mg (1 capsule) per day; b. Hetlioz LQ: 0.7 mg per kg per day if weight \leq 28 kg, 20 mg per day if weight $>$ 28 kg.

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:

1. Hetlioz Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; December 2020. Available at: www.hetlioz.com. Accessed March 24, 2021.
2. National Sleep Foundation. Non-24-Sleep Wake Disorder Facts and Prevalence.
3. Morgenthaler TI, Lee-Chong T, et al. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine report. *Sleep*. 2007;30(11):1445-1459.
4. American Academy of Sleep Medicine. International Classification of Sleep Disorders. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014 Auger RR, Burgess HJ, et al. Clinical Practice Guidelines for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Phase Disorder (DSWPD), Non-24-hour Sleep Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD) *J Clin Sleep Med* 2015;11(10):1199-1236.
5. Wyatt JK. Overview of circadian sleep-wake rhythm disorders. UpToDate. Waltham, MA. Rev Sep 2016.

Covered products	Brand or generic Name
HORIZANT	gabapentin enacarbil extended-release tablets

CRITERIA FOR COVERAGE/NONCOVERAGE

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:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu>. Accessed 03/2019.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: <http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/>. 03/2019..
 3. Horizant prescribing information. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised 10/2016.
 4. Winkelman JW, Armstrong MJ. Practice guideline summary: Treatment of restless legs syndrome in adults Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. Dec 2016;Vol. 87; no. 24;2585-2593. <https://www.ncbi.nlm.nih.gov/pubmed/27856776?dopt=Abstract>
5. Dubinsky RM, Kabbani H, et al. Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. Sep 2004 vol. 63 no. 6;959-965.
 6. Johnson RW, Rice A, et al. Postherpetic Neuralgia. *N Engl J Med* 2014;371:1526-33.
7. Restless Legs Syndrome Rating Scale The International Restless Legs Syndrome Study Group. Validation of the International Restless Legs Syndrome Study Group Rating Scale for restless legs syndrome. *Sleep Med* 2003;4(2):121-132. www.rls.org.au/pdf/PKGD6.pdf.
8. Bell, Amanda, Fashner, Julia. Herpes Zoster and Postherpetic neuralgia: Prevention and Management. *Am Fam Physician*. 2011 Jun 15; 83(12):1432-1437. <https://www.aafp.org/afp/2011/0615/p1432.html#sec-5>. Accessed on 03/2019.

Brand Name	Generic Name
H.P. Acthar Gel	Corticotropin Injection
CRITERIA FOR COVERAGE/NON-COVERAGE	

H.P. Acthar Gel is an adrenocorticotrophic 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:

1. H.P. Acthar Gel prescribing information. Hazelwood, MO. Mallinckrodt Pharmaceuticals Inc. Rev Jul 2017.
2. Micromedex/DRUGDEX at www.microdexsolutions.com.
3. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.

Brand Name	Generic Name
HUMIRA	adalimumab
ENBREL	etanercept
XELJANZ IR tabs and oral solution	tofacitinib
OTEZLA	apremilast

CRITERIA FOR COVERAGE/NON-COVERAGE

Humira, Enbrel, Xeljanz IR and Otezla will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. Rheumatoid Arthritis (HUMIRA, ENBREL AND XELJANZ IR ONLY)

- Prescribed by or in consultation with a rheumatologist.
- Age ≥ 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or prescriber attestation.
- Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
 - Methotrexate
 - Hydroxychloroquine
 - Leflunomide
 - Sulfasalazine
- Requests for XELJANZ IR will also require recent labwork for renal function, hepatic function, absolute neutrophil count, absolute lymphocyte count and hemoglobin.

2. Juvenile Idiopathic Arthritis (HUMIRA, ENBREL and XELJANZ oral solution and IR tablets ONLY)

- Prescribed by or in consultation with a rheumatologist.
- Age ≥ 2 years and current weight is ≥ 10 kg (Humira, **Xeljanz oral solution or IR tablets ONLY**).
- Documentation submitted member has no latent or active tuberculosis infection.
- Diagnosis of moderate to severe rheumatoid arthritis (RA) with at least five swollen joints and at least three joints with limitation of motion
- Trial and failure of **one** of the following therapies unless intolerant or contraindicated
 - Methotrexate for at least 30 days
 - Oral NSAID for at least 30 days
 - Oral corticosteroid for at least 14 days
- Requested dose and dosing interval is consistent with the FDA labeled recommended dosing.
- Requests for XELJANZ IR will also require recent labwork for renal function, hepatic function, absolute neutrophil count (ANC), absolute lymphocyte count, and hemoglobin (hgb).

3. Plaque Psoriasis (HUMIRA, ENBREL, AND OTEZLA ONLY)

- a. Prescribed by or in consultation with a dermatologist or rheumatologist.
- b. Age ≥ 18 years for Humira and Otezla. Age ≥ 4 years old for Enbrel.
- c. Documentation submitted member has no latent or active tuberculosis infection (Humira and Enbrel only).
- d. Documented diagnosis of **moderate to severe** plaque psoriasis with $\geq 10\%$ of body surface area (BSA) affected.

Note: An exception to the $\geq 10\%$ 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:
 - v. Calcipotriene (generic for Dovonex) topical preparations
 - vi. 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.
 - vii. Tacrolimus 0.1% (prior authorization required) ointment
 - viii. 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:
 - iii. Methotrexate oral tablets
 - iv. Cyclosporine oral capsules

4. Psoriatic Arthritis (HUMIRA, ENBREL, OTEZLA AND XELJANZ IR)

- a. Prescribed by or in consultation with a rheumatologist.
- b. Age ≥ 18 years.
- c. Documentation submitted member has no latent or active tuberculosis infection (Humira, Enbrel and Xeljanz only).
- 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
 - v. Sulfasalazine
- f. Requests for XELJANZ IR will also require recent labwork for renal function, hepatic function, absolute neutrophil count, absolute lymphocyte count and hemoglobin.

5. Ankylosing Spondylitis (HUMIRA AND ENBREL ONLY)

- 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*

6. Crohn's Disease (pediatric and adult) (HUMIRA ONLY)

- 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 (HUMIRA AND XELJANZ IR ONLY)

- a. Prescribed by or in consultation with a gastroenterologist.
- b. Age ≥ 5 years old for Humira and age ≥ 18 years old for Xeljanz IR
- 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. Requests for XELJANZ IR will also require recent labwork for renal function, hepatic function, absolute neutrophil count, absolute lymphocyte count and hemoglobin.

8. Hidradenitis Suppurativa (HS) (HUMIRA ONLY)

- 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

9. Non-infectious Intermediate, posterior uveitis or panuveitis (HUMIRA ONLY)

- 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.

10. Behçet disease (OTEZLA ONLY)

- a. Documented diagnosis of Behçet disease
- b. 12 week trial and failure of, or contraindication to ALL of the following:
 - i. intra-oral topical steroids
 - ii. colchicine
 - iii. one or more of the following:
 - azathioprine
 - thalidomide
 - interferon-alpha
 - iv. one or more of the following:
 - systemic dapsone
 - azithromycin

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

Quantity Limits:

- 1. **Crohn's Disease:**
 - A. HUMIRA: One starter package containing 6 pens will initially be authorized for a 21-day supply, followed by 2 syringes per 28 days thereafter.
- 2. **Ulcerative Colitis:**
 - A. HUMIRA: One starter package containing 6 pens will initially be authorized for a 21-day supply, followed by 2 syringes per 28 days thereafter.
 - B. XELJANZ IR: #60 tablets per 30 days.

3. **Hidradenitis Suppurativa:**
 - A. HUMIRA: One starter package containing 6 pens will initially be authorized for a 21-day supply, followed by 4 syringes per 28 days thereafter
4. **Pediatric Crohn's Disease:**
 - A. HUMIRA:
 - a. Members < 40 kg: One starter package containing 3 syringes will initially be authorized for a 21-day supply, followed by 20 mg syringe – 2 syringes per 28 days thereafter.
 - b. Members \geq 40 kg: One starter package containing 6 syringes will initially be authorized for a 21-day supply, followed by 40 mg pen or syringe – 2 syringes per 28 days thereafter
5. **Ankylosing spondylitis:**
 - A. HUMIRA: 2 per 28 days
 - B. ENBREL:
 - a. 25mg syringe: 8 per 28 days
 - b. 50mg syringe: 4 per 28 days
6. **Juvenile Idiopathic Arthritis**
 - A. HUMIRA: 2 per 28 days
 - B. ENBREL:
 - a. 25mg syringe: 8 per 28 days
 - b. 50mg syringe: 4 per 28 days
 - C. XELJANZ Oral Solution (1mg/mL): up to 240mL per 30 days (twice a day dosing)
 - D. XELJANZ IR tabs: 60 tablets per 30 days (twice a day dosing)
 - E.
7. **Psoriatic Arthritis:**
 - A. HUMIRA: 2 per 28 days
 - B. ENBREL:
 - a. 25mg syringe: 8 per 28 days
 - b. 50mg syringe: 4 per 28 days
 - C. XELJANZ IR: #60 tablets per 30 days
 - D. OTEZLA: #60 tablets per 30 days
8. **Rheumatoid Arthritis:**
 - A. HUMIRA: 2 per 28 days
 - B. ENBREL: 4 per 28 days
 - C. XELJANZ IR: #60 tablets per 30 days
9. **Plaque psoriasis :**
 - A. HUMIRA: One starter package containing 4 syringes will initially be authorized for a 28-day supply, followed by 2 syringes per 28 days thereafter
 - B. ENBREL:
 - a. 25mg syringe: 16 per 28 days x 12 weeks then 8 per 28 days thereafter
 - b. 50mg syringe: 8 per 28 days x 12 weeks then 4 per 28 days thereafter
 - C. OTEZLA: #60 tablets per 30 days

10. **Uveitis:**

- A. HUMIRA: One starter package containing 4 syringes will initially be authorized for a 28 days supply, followed by 2 syringes per 28 days thereafter.

11. **Behçet Disease:**

- A. OTEZLA: #60 tablets per 30 days

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.

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.

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:

1. Van der Heijde D, Ramiro S, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Annals of the Rheumatic Diseases*. 2017;76:978-991.
2. Singh J, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.
3. Lovell DJ, Ruperto N, et al. Adalimumab with or without Methotrexate in Juvenile Rheumatoid Arthritis. *N Engl J Med*. 359:810-820 Aug 2018.
4. Ward MM, Deodhar A, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology*. 2015.
5. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010.
6. Ringold S, Weiss P, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. *Arthritis & Rheumatism*. Vol 65(10);Oct 2013,2499-2512.
7. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
8. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.
9. Lichtenstein GR, Loftus EV, et al. ACG Clinical Guidelines: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018 Apr;113(4):481-517.
10. Humira Prescribing information. North Chicago, IL. AbbVie Inc. Rev Dec 2017.
11. Otezla prescribing information. Summit, NJ. Celgene Corporation. Rev Jun 2017.
12. Xeljanz prescribing information. New York, N.Y. Pfizer Inc. Rev May 2018.
13. Enbrel prescribing information. Thousand Oaks, CA. Amgen. Rev Nov 2017.

Covered 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:

1. Humulin R U-500 Insulin prescribing information. Indiana, IN. Eli Lilly and Co. Rev Oct 2016.
2. Cefalu WT. American Diabetes Association Standards of Medical Care in Diabetes – 2017. *Diabetes Care*. Jan 2017;40(Suppl. 1):S72-S73.
3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 7/2017
4. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 7/2017

Nonformulary	
Brand Name	Generic Name
ILARIS	canakinumab

CRITERIA FOR COVERAGE/NONCOVERAGE
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Ilaris is an interleukin-1 β 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

1. Micromedex/DRUGDEXatwww.microdexsolutions.com.
2. Facts&ComparisonseAnswersat<http://online.factsandcomparisons.com>.

Brand Name	Generic Name
IMCIVREE	setmelanotide

CRITERIA FOR COVERAGE/NONCOVERAGE

Imcivree is a melanocortin-4 receptor (MC4R) agonist that activates the MC4R in the brain to regulate energy expenditure and appetite. Imcivree (setmelanotide) is indicated for chronic weight management in adult and pediatric patients aged 6 and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1) or leptin receptor (LEPR) deficiency confirmed by genetic testing.

Prevalence of POMC/PCSK1 deficiency is estimated to be 100-500 patients in the U.S and LEPR deficiency estimated to be 500-2,000 patients in the U.S.

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

Initial criteria:

1. Prescribed by, or in consultation with, an endocrinologist or geneticist.
2. Member is in consultation with a dietitian or nutritionist and is enrolled in an exercise program.
3. Member is 6 years of age or older.
4. Member has a documented diagnosis of obesity due to deficiency of proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) gene.
5. Obesity documented and defined as one of the following:
 - a. Adult patients: BMI ≥ 30 kg/m²
 - b. Pediatric patients (6-17 years): Weight $\geq 95^{\text{th}}$ percentile
6. Documentation submitted of genetic test laboratory report supporting a variant in POMC, PCSK1, or LEPR gene that is interpreted to be pathogenic, likely pathogenic, or of uncertain significance.

Note: Direct to consumer (DTC) genetic testing not acceptable as these tests do not determine if the gene variant is disease-causing.
7. Baseline (within the past 30 days) weight and BMI is submitted.
8. Documentation submitted supporting no moderate to severe renal impairment present.

Initial Approval Duration: 12 weeks (3 months)

Continuation criteria:

1. Submission of clinical documentation attesting to at least 5% weight loss from baseline body weight (or at least 5% BMI from baseline in patients with continued growth potential) is required after initial 12 weeks.
2. After 1 year of treatment $\geq 10\%$ reduction or maintenance in weight compared to baseline.
3. Member is in consultation with a dietitian or nutritionist and continues to be enrolled in an exercise program.
4. Member has been adherent per prescription claims history.

Renewal Duration: 12 months

Dosage:**Age 12 years and older**

- Initial dosage: 2 mg (0.2 mL) subQ once daily for 2 weeks, monitoring for GI adverse reactions.
- Dosage titration: If the starting dose is not tolerated, reduce to 1 mg (0.1 mL) once daily. If the 1 mg once daily dose is tolerated and additional weight loss is desired, titrate to 2 mg (0.2 mL) once daily. If the 2 mg daily dose is tolerated and additional weight loss is desired, increase the dose to 3 mg (0.3 mL) once daily. If the 3 mg once daily dose is not tolerated, maintain administration of 2 mg (0.2 mL) once daily.
- Discontinue therapy after 12 to 16 weeks of treatment if patient has not lost at least 5% of baseline body weight or 5% of baseline BMI for patients with continued growth potential.

Age 6 to less than 12 years

- Initial dosage: 1 mg (0.1 mL) subQ once daily for 2 weeks, monitoring for GI adverse reactions.
- Dosage titration: If the starting dose is not tolerated, reduce to 0.5 mg (0.05 mL) once daily. If the 0.5 mg once daily dose is tolerated and additional weight loss is desired, the dose may be increased to 1 mg (0.1 mL) once daily. If the 1 mg dose is tolerated, increase the dose to 2 mg (0.2 mL) once daily. If the 2 mg once daily dose is not tolerated, reduce to 1 mg (0.1 mL) once daily. If the 2 mg once daily dose is tolerated and additional weight loss is desired, the dose may be increased to 3 mg (0.3 mL) once daily.
- Discontinue therapy after 12 to 16 weeks of treatment if patient has not lost at least 5% of baseline body weight or 5% of baseline BMI for patients with continued growth potential.

Exclusions/Limitations:

Imcivree is not indicated for the treatment of patients with the following conditions as Imcivree would not be expected to be effective, therefore these uses will not be approved:

- Obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign.
- Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity.

References:

1. [Imcivree prescribing information. Boston, MA. Rhythm Pharmaceuticals, Inc. Rev Nov 2020.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213793s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213793s000lbl.pdf)
2. Clément K et al. *Lancet Diabetes Endocrinol.* 2020;8(12):960-970. <https://pubmed.ncbi.nlm.nih.gov/33137293/>
3. Kleinendorst L, Abawi O, et al. Leptin receptor deficiency: a systematic literature review and prevalence estimation based on population genetics. *Eur J Endocrinol.* 2020 Jan;182(1):47-56.

Brand Name	Generic Name
INCRELEX	mecasermin

CRITERIA FOR COVERAGE/NONCOVERAGE

INCRELEX/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 \leq -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 \leq the 25th percentile (defined as 68 inches in males and 63 inches in females).

****Authorization is for 12 months**

References

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

NONFORMULARY	
Brand Name	Generic Name
INGREZZA	valbenazine

CRITERIA FOR COVERAGE/NON-COVERAGE

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

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*)

Class	Drugs within the class		
First Generation Anti-psychotics (FGAs)	chlorpromazine	loxapine	prochlorperazine
	chlorprothixene	mesoridazine	thioridazine
	droperidol	molindone	thiothixene
	fluphenazine	perazine	trifluoperazine
	flupentixol	perphenazine	triflupromazine
	haloperidol	pimozide	zuclopentixol
	levomepromazine		
Second Generation Anti-psychotics (SGAs)	amisulpride	levosulpiride	remoxipride
	aripiprazole	lurasidone	risperidone
	asenapine	olanzapine	sulpiride
	clozapine	paliperidone	tiapride
	iloperidone	quetiapine	ziprasidone

Antiemetics	cisapride clebopride metoclopramide
Calcium Channel Blockers	cinnarizine flunarizine
Serotonin reuptake/serotonin norepinephrine reuptake inhibitors	duloxetine citalopram
Tricyclic antidepressants	amoxapine
Central monoamine oxidase inhibitors	reserpine
Anti-manic agents	lithium sulpiride veralipride

References:

1. AIMS: Abnormal Involuntary Movements Scale www.cqaimh.org/pdf/tool_aims.pdf
2. Bhidayasiri R, Fahn S, et al. Evidence-based guideline: Treatment of tardive syndromes: Report of the guidelines development subcommittee of the American Academy of Neurology. *Neurology*. 2013;81;463-469.
3. Ingrezza prescribing information. San Diego, CA. Neurocrine Biosciences, Inc.; Apr 2017.
4. American Psychiatric Association (2013). Medication-induced movement disorders and other adverse effects of medication. In
Diagnostic and statistical manual of mental disorders (5th ed.). Available at:
www.dx.doi/full/10.1176/appi.books.9780890425596.MedicationInduced#x45151.2829056
5. Hauser R, et al. KINECT-3: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Valbenazine for Tardive Dyskinesia. *American Journal of Psychiatry*. 2017 Mar 21: 1-9.
6. Vijayakumar D, Jankovic J. Drug-induced dyskinesia, part 2: Treatment of tardive dyskinesia. *Drugs*. 2016;76:779-787.
7. Chouinard G, Margoless HC. Manual for the Extrapyramidal Symptom Rating Scale (ESRS). *Schizophrenia Research* 76 (2005) 247 – 265.
8. Gharabawi GM, Bossie CA, et al. Abnormal Involuntary Movement Scale (AIMS) and Extrapyramidal Symptom Rating Scale (ESRS): cross-scale comparison in assessing tardive dyskinesia. *Schizophr Res* 2005 Sep 15;77(2-3):119-28.

Covered Product	Reference BRAND or Generic Name
PULMOZYME®	Dornase alfa
Bethkis – Preferred product	Tobramycin nebulization
Kitabis PAK – Preferred product	Tobramycin nebulization
Tobramycin INH – <i>NON Preferred</i>	TOBI® INHALATION <i>NON Preferred</i>
TOBI POD HALER – <i>NON Preferred</i>	
Cayston-Non Preferred	Aztreonam

CRITERIA FOR COVERAGE/NON COVERAGE

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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 05/2019
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 05/2019
3. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013;187(7):680-689.

Brand Name	Generic Name
INTRON [®] A	Interferon alfa-2b

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdextrsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Product	Reference Brand
Itraconazole	SPORANOX

CRITERIA FOR COVERAGE/NONCOVERAGE

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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2019.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 03/2019.

Non Formulary	
Brand Name	Generic Name
JULUCA	Dolutegravir/Rilpivirine

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:

1. Juluca prescribing information. Research Triangle Park, NC. GlaxoSmithKline. Rev Dec 2017.

Brand Name	Generic Name
JUXTAPID™	Lomitapide mesylate

CRITERIA FOR COVERAGE/NONCOVERAGE
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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 tendonous 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

3. Micromedex/DRUGDEX at www.microdexasolutions.com. Accessed 11/2016
4. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

NONFORMULARY	
Brand Name	Generic Name
KALYDECO tablets and oral granules	ivacaftor
ORKAMBI tablets and granules	lumacaftor/ivacaftor
SYMDEKO tablets	tezacaftor/ivacaftor
TRIKAFTA tablets	elexacaftor/tezacaftor/ivacaftor

CRITERIA FOR COVERAGE/NON-COVERAGE

Kalydeco is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 4 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 6 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.

Trikafta, a combination of Elexacaftor/tezacaftor/ivacaftor, is indicated for the treatment of CF in patients aged 6 years and older with at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data.

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 \geq 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. Member has diagnosis of cystic fibrosis (CF) with one of the following confirmed by FDA approved CF mutation test:

5. Member has at least one of following mutations in the CFTR gene that is responsive to Kalydeco: See prescribing information for complete list of responsive CFTR mutations https://pi.vrtx.com/files/uspi_ivacaftor.pdf
- ii. Kalydeco granules: Age 4 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

Member has diagnosis of cystic fibrosis (CF) with one of the following confirmed by

FDA approved CF mutation test:

1. Member has at least one of following mutations in the CFTR gene that is responsive to Symdeko: See prescribing information for complete list of responsive CFTR mutations https://pi.vrtx.com/files/uspi_tezacaftor_ivacaftor.pdf
- ii. Member is homozygous for F508del mutation in the CFTR gene
- iii. Member is age 6 years or older.

d. Trikafta

- i. Member has diagnosis of cystic fibrosis (CF) with at least one F508del mutation in the CFTR gene a mutation in the CFTR gene that is responsive based on in vitro data. See prescribing information for complete list of responsive CFTR mutations https://pi.vrtx.com/files/uspi_ellexacaftor_tezacaftor_ivacaftor.pdf
- ii. Member is age 6 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, *Trikafta* – 84 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 OR
 - d. Provider attestation of benefit from therapy
2. 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:

1. Kalydeco prescribing information. Boston, MA. Vertex Pharmaceuticals Inc. April 2018. Accessed 05/2019.
2. Orkambi prescribing information. Boston, MA. Vertex Pharmaceuticals Inc. Aug 2018.
3. Symdeko prescribing information. Boston, MA. Vertex Pharmaceuticals Inc. Feb 2018.
4. Trikafta prescribing information. Boston, MA. Vertex Pharmaceuticals Inc. Sept 2020.
5. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medication for maintenance of lung health. Am J Respir Crit Care med. 2013; vol 187, issue (7):680-689.
<https://www.atsjournals.org/doi/pdf/10.1164/rccm.201207-1160OE>. Accessed 05/2019.

Non Formulary	
Brand Name	Generic Name
KEVZARA	sarilumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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 \geq 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 as attested by the prescriber.
- 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. Recent lab documentation submitted of hepatic function, absolute neutrophil count (ANC), and platelets.
- h. 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.

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 Health Choice****

References:

1. Kevzara prescribing information. Bridgewater, NJ. Sanofi-Aventis U.S. LLC. Rev Apr 2018
2. Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2016 Jan;68(1):1-25.

Brand Name	Generic Name
LEUKINE	sargramostim

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

4. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
5. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 03/2017

Covered Product	Brand Reference
Lidocaine 5% Ointment	XYLOCAINE

CRITERIA FOR COVERAGE/NONCOVERAGE
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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 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:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 02/2017
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 02/2017

Brand Name	Generic Name
LINZESS	linaclotide

CRITERIA FOR COVERAGE/NONCOVERAGE

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:

1. Linzess prescribing information. Cambridge, MA. Ironwood Pharmaceuticals. Rev Mar 2017.
2. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 07/2017.
3. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 07/2017.
4. Bharucha A, Pemberton, JH, et al. American Gastroenterological Association Technical Review on Constipation. *Gastroenterology* 2013;144:218-238.

LONG-ACTING OPIOIDS	
PREFERRED PRODUCTS:	NON-PREFERRED PRODUCTS:
Butrans patches (brand name)	Belbuca, Exalgo, Fentanyl (37.5mcg, 62.5mcg, 87.5mcg)
Fentanyl patches (certain strengths)	Hydromorphone ER, Hysingla, Kadian ER, Methadone,
Morphine Sulfate ER tablets	Morphine Sulfate ER capsules, Nucynta ER, Oxycontin,
Tramadol ER tablets	Oxycodone ER tabs, Oxymorphone ER, Zohydro ER
Xtampza ER capsules	

CRITERIA FOR COVERAGE/NON-COVERAGE

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, chiropractic, 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.^{1, 2, 3}

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 $\geq 100\text{mg}/4\text{mg}$
 - Any strength of Fentanyl patches
 - Morphine daily dose $\geq 60\text{mg}$
 - Any strength of hydromorphone ER
 - Oxycodone ER/Oxycontin daily dose $\geq 80\text{mg}$
 - Xtampza ER daily dose $\geq 72\text{mg}$
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):

6. Butrans patches - #4/28 days
7. Fentanyl patches - #15/30 days
8. Morphine sulfate ER tablets - #90/30 days

9. Xtampza ER - #60/30 days
10. 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:

1. AHCCCS Medical Policy Manual. Quality Management and Performance Improvement Program Chapter 900, Policy 960.
2. Arizona Opioid Prescribing Guidelines, 2019. <https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf>
3. Dowell D, Haegerich TM, et al. CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016. *MMWR Recomm Rep* 2016; 65(No.RR-1):1-49. Available at: www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
4. www.micromedexsolutions.com Accessed 8/2017.
5. <http://eanswers.factsandcomparisons.com/index.aspx> Accessed 8/2017.
6. <http://www.azleg.gov/ars/36/02606.htm>.
7. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington, VA: American Psychiatric Publishing; 2013.
8. U.S. Government Printing Office. (2006). Code of Federal Regulations. Washington, DC: GPO.

Brand Name	Generic Name
LUPRON DEPOT	Leuprolide acetate
LUPRON DEPOT-PED	Leuprolide acetate
ELIGARD	Leuprolide acetate

CRITERIA FOR COVERAGE/NON-COVERAGE

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:

Lupron Depot: 1-month (3.75 mg, 7.5 mg)
 3-month (11.25 mg, 22.5 mg)
 4-month (30 mg)
 6-month (45 mg)

Lupron Depot-Ped: 1-month (7.5 mg, 11.25 mg, 15mg)
 3-month (11.25 mg, 15 mg)

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:

1-month (7.5 mg)

3-month (22.5 mg)

4-month (30 mg)

6-month (45 mg)

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:
 - a. Agreement with the indication for GnRH agonist treatment.
 - b. Has confirmed puberty has started in the adolescent (Tanner stage \geq 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. Micromedex/DrugDex Compendium with a ***Class I, IIa, or IIb rating***.

- iii. Elsevier Gold Standard's Clinical Pharmacology Compendium with a ***strong recommendation***.
 - iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and 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:

1. Lupron Depot prescribing information. North Chicago, IL. Abbvie Inc. Rev May 2017.
2. Lupron Depot-Ped prescribing information. North Chicago, IL. Abbvie Inc. Rev May 2017.
3. Practice Committee of the American Society for Reproductive Medicine. Treatment of pelvic pain associated with endometriosis: A committee opinion. *Fertil Steril*. 2014 Apr;101(4):927-35.
4. Kaplowitz PB, Bloch CA. Evaluation and Referral of Children with Signs of Early Puberty. *Pediatrics*. Jan 2016 Vol 137(1).
5. Micromedex/DrugDex System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA.
6. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017.
7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
8. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&_
9. Walch K, Unfried G, et al. Implanon versus medroxyprogesterone acetate: Effects on pain scores in patient with symptomatic endometriosis – a pilot study. *Contraception*. 2009;79(1):29.
10. Yisa SB, Okenwa AA, et al. Treatment of pelvic endometriosis with etonogestrel subdermal implant (Implanon). *J Fam Plann Reprod Health Care*. 2005;31(1):67.
11. Hembree WC, Cohen-Kettenis PT, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. Nov 2017, 102(11):3869-3903.

12. Eligard prescribing information. Fort Collins, CO. Tolmar Pharmaceuticals Inc. Rev Jul 2016.
13. <http://www.ogsm.org.my/docs/Endometriosis-guideline.pdf>
14. Management of Endometriosis. *Obstetrics & Gynecology*. 2010 July;116(1):223-236.
15. UpToDate (electronic version). Wolters Kluwer.
16. Moroni RM, Vieira CS, Ferriani RA, Candido-dos-Reis, Brito LGO. Pharmacological Treatment of Uterine Fibroid. *Ann Med Health Sci Res*. 2014 Sep-Oct; 4(Suppl 3): S185-S192.

NONFORMULARY	
Brand Name	Generic Name
LYRICA, LYRICA CR	Pregabalin

CRITERIA FOR COVERAGE/NONCOVERAGE

BRAND LYRICA (pregabalin) 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 if stated:

LYRICA:

Note- The member must have first tried, failed, or have a documented contraindication to a compliant 60-day trial of the generic product (Pregabalin immediate-release).

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 \geq 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 \geq 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 \geq 1800mg/day for at least 90 days.

LYRICA CR:

Note- The member must have first tried, failed, or have a documented contraindication to a compliant 60 day trial of the generic product (Pregabalin controlled-release).

1. Neuropathic pain associated with diabetic peripheral neuropathy
 - a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose \geq 1800mg/day for at least 90 days.
2. Postherpetic neuralgia
 - a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose \geq 1800mg/day for at least 90 days.

Quantity Level Limits:

1. For the following strengths: 25mg/50mg/75mg/100mg/150mg/200mg, QL is #90 every 30 days

2. For the following strengths: 225mg/300mg, QL is #60 every 30 days
3. For the following strengths: 82.5mg/165mg/330mg, QL is #30 every 30 days

Initial and renewal 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

5. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 6/2021
6. Facts& ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 6/2021

Brand Name	Generic Name
MAKENA	Hydroxyprogesterone caproate injection

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 10/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 10/2016

Criteria Name
Cumulative Morphine Equivalent Dose DUR Exceptions

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain: An educational aid to improve care and safety with opioid therapy. Available at: <http://agencymeddirectors.wa.gov/Files/OpioidGdline.pdf>. Accessed 8/17/2012.
2. Chou R, Fanciullo GJ, Fine PG, et al; American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain* 2009; 10:113-130.
3. Jamison, Robert. Substance abuse treatment for high risk chronic pain patients on opioid therapy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 7/22/2011. Available from: <http://clinicaltrials.gov/ct2/show/NCT00988962>. NCT00988962.
4. Manchikan L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance. *Pain Physician*. 2012; 15:S67-S115. Micromedex Healthcare Series. Available at <http://www.thomsonhc.com/home/dispatch>. Accessed August 28, 2012.

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:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu>. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: <http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/>. 9/9/17.
3. Namenda prescribing information. Irvine, CA. Allergan USA, Inc. Rev Aug 2016.
4. Folstein MF, Folstein SE, et al. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-198. www.dementiatoday.com/wp-content/uploads/2012/06/MiniMentalStateExamination.pdf
5. Doody RS, Stevens JC, et al. Practice parameter: Management of dementia (an evidence-based review).
6. Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. May 2001;Vol 56;no 9;1154- 1166.

NON FORMULARY	
Covered Product	Brand Reference
modafinil	PROVIGIL

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 03/2017
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 03/2017

MULTIPLE SCLEROSIS INJECTABLE MEDICATIONS	
Brand Name	Generic Name
COPAXONE 20mg (brand name only)	Glatiramer acetate 20mg
GLATOPA 40mg	Glatiramer acetate 40mg
AVONEX	Interferon beta-1a
BETASERON	Interferon beta-1b
REBIF Rebidose	Interferon beta-1a
PLEGRIDY	Peginterferon beta-1a

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.
3. Documented clinical diagnosis of a relapsing form of multiple sclerosis.

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 appear¹*
- **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 point²*
- **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 remissions¹*
- **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 recovery¹*

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:

1. Hooper K. Managing Progressive MS. New York, NY: National Multiple Sclerosis Society 2011.
2. Multiple Sclerosis: Just the Facts New York, NY; National Multiple Sclerosis Society 2011.
3. Avonex prescribing information. Cambridge, MA. Biogen Inc. Rev Oct 2015.
4. Betaseron prescribing information. Whippany, NJ. Bayer Healthcare Pharmaceuticals. Rev Apr 2016.
5. Plegridy prescribing information. Cambridge, MA. Biogen Inc. Rev Oct 2015.
6. Copaxone prescribing information. Overland Park, MO. Teva Neuroscience Inc. Rev Aug 2016.
7. Rebif prescribing information. Rockland, MA. EMD Serono. Rev Oct 2015.
8. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, CO, USA.
9. Facts and Comparisons eAnswers [database online]. Hudson, OH. Wolters Kluwer Clinical Drug Information, Inc 2017.

MULTIPLE SCLEROSIS ORAL MEDICATIONS	
Brand Name	Generic Name
GILENYA	Fingolimod
TECFIDERA	Dimethyl fumarate
AUBAGIO	Teriflunomide
Dimethyl fumarate	
Vumerity (non-formulary)	diroximel fumarate (non-formulary)

CRITERIA FOR COVERAGE/NON-COVERAGE

Gilenya is a sphingosine 1-phosphatase receptor modulator in an oral capsule indicated for the treatment of relapsing forms of multiple sclerosis (MS).

Tecfidera (dimethyl fumarate) 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.

Vumerity is a nuclear factor-like 2 activator and is 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.
3. Documented clinical diagnosis of a relapsing form of multiple sclerosis.

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 appear⁴
- **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 point⁵
- **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 remissions⁴

- **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 recovery⁴
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 ≥ 500 ms.

Tecfidera

1. Request is for Tecfidera to be taken twice a day.
2. Member has a documented trial and failure of generic Tecfidera (Dimethyl Fumarate)

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

Vumerity

1. Request is for two capsules to be taken twice a day.
2. There was inadequate response, intolerable side effects, or contraindication to all preferred MS agents.

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:

1. Gilenya prescribing information. East Hanover, NJ. Novartis. Rev Oct 2018.
2. Tecfidera prescribing information. Cambridge, MA. Biogen, Inc. Rev Jan 2017.
3. Aubagio prescribing information. Cambridge, MA. Genzyme Corp. Rev Nov 2016.
4. Vumerity Prescribing Information. Cambridge, MA: Biogen Inc.; January 2021. Available at <http://www.vumerity.com>. Accessed June 16, 2021.
5. Hooper K. Managing Progressive MS. New York, NY. National Multiple Sclerosis Society 2011.
6. Multiple Sclerosis: Just the Facts New York, NY. National Multiple Sclerosis Society 2011.
7. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, CO, USA.
8. Facts and Comparisons eAnswers [database online]. Hudson, OH. Wolters Kluwer Clinical Drug Information, Inc 2017.

Brand Name	Generic Name
MYALEPT	metreleptin

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 05/2019
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 05/2019
3. UpToDate. Lipodystrophic syndromes. Accessed 05/2019

Brand Name	Generic Name
MYCAPSSA oral capsules	octreotide

CRITERIA FOR COVERAGE/NON-COVERAGE

Mycapssa is a somatostatin analogue FDA indicated for:

- Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

Mycapssa is available as a 20 mg oral capsule. The recommended starting dose is 20 mg twice daily and maximum recommended dosage is 80mg daily

Initial approval criteria:

Acromegaly

1. Prescribed by, or in consultation with an endocrinologist.
2. Member is 18 years of age or older.
3. Documentation confirming diagnosis of **acromegaly** with laboratory report based on laboratory reference range of high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender.
4. Documentation of inadequate or partial response to surgery or radiotherapy, or clinical reason submitted supporting clinically why surgery or radiotherapy is not an option. Clinical reasons may include:
 - a. Poor surgical candidate or refuse surgery
 - b. Have an adenoma that is not fully resectable
5. Documentation of clinical failure at a maximally tolerated dose after adequate 30 day trial, intolerance to, or contraindication to, **bromocriptine** oral tablets.
6. If mild symptoms, documentation of clinical failure at a maximally tolerated dose after adequate 30 day trial, intolerance to, or contraindication to, **cabergoline** oral tablets or other dopamine agonist.
7. Documentation of clinical failure of, or physical or mental (phobia) inability of use of **Bynfezia self-injectable pen**. Clinical failure defined as lack of significant decrease or normalization in IGF-1 level since adherent initiation of Bynfezia.
8. Documentation of clinical failure of, or mental (phobia) inability of use of **Sandostatin Depot** long acting (octreotide) or **Somatuline Depot** (lanreotide) provider administered injection.
9. Requested dose and dosing will not exceed 80 mg daily or exceed a dosing interval of twice daily.

Initial and Continuation Approval Duration: 6 months

Continuation criteria:

Acromegaly –

1. Documentation submitted supporting decrease or normalization in IGF-1 level since initiation of therapy.

Quantity Limits: Up to a maximum of 80mg per day (4 capsules per day or 120 capsules per month).

References:

1. Mycapssa prescribing information. Scotland, UK. MW Encap Ltd. Rev Jun 2020.
2. Melmed S, Katznelson L, et al. Treatment of acromegaly. Waltham, MA. UpToDate, Inc. Rev Apr 2020.
3. Katznelson L, Laws ER, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* Nov 2014. 99(11):3933-3961.
4. The Journal of Clinical Endocrinology and Metabolism clinical practice guidelines
5. Facts and Comparisons Clinical Practice Guidelines

Brand Name	Generic Name
MYTESI (formerly Fulyzaq)	crofelemer

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 5/2019
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 5/2019

Brand Name	Generic Name
NEUPOGEN	filgrastim

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEXatwww.microdexsolutions.com.
2. Facts& ComparisonseAnswersat<http://online.factsandcomparisons.com>.
3. Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen; June 2016.

Brand Name	Generic Name
NEVANAC®	Nepafenac 0.1%

CRITERIA FOR COVERAGE/NONCOVERAGE
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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:

3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
4. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. 11/2016
5. American Academy of Ophthalmology at <http://www.aao.org> Accessed 11/2016

Criteria Name
Prescriber not on Behavioral Health List

CRITERIA FOR COVERAGE/NONCOVERAGE
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When a request is submitted to the plan for coverage of an antipsychotic prescribed by a non-BH provider, coverage may be granted when the following criteria 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.

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. **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.
2. **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.***
 - iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and 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 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

The MedWatch form for healthcare professionals can be found at:

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:

1. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
3. American Society of Clinical Oncology (ASCO). ASCO Guidelines, Tools, & Resources. 2017.
4. Facts & Comparisons Answers. Available at: <http://online.factsandcomparisons.com> Accessed 7/2017.
5. Micromedex/DRUGDEX. Available at: www.micromedexsolutions.com Accessed 7/2017.
6. Arizona Health Care Cost Containment System. AHCCCS Medical Policy Manual. Policy 310-V Prescription Medications/Pharmacy Services. Rev 2/1/2017.

Brand Name	Generic Name
NORTHERA (Non-formulary)	Droxidopa (PA required)

CRITERIA FOR COVERAGE/NONCOVERAGE

*****Effective 4/1/2021, generic is available. Brand is Non-formulary product*****

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. If request is for Brand Northera, member must have an adequate trial and failure of generic droxidopa first, unless contraindicated.
7. 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 2 weeks; efficacy beyond 2 weeks has not been established.

Reauthorization will only be approved if evidence of efficacy beyond 2 weeks is submitted AND requires confirmation the following:

- Patient had improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint or feeling like patient may black out
- Patient will be monitored for supine hypertension during treatment (systolic blood pressure (SBP) >180 mmHg or diastolic blood pressure (DBP) >110 mmHg)

References

3. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 05/2019
4. Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 05/2019
5. UpToDate. Treatment of orthostatic and postprandial hypotension. Accessed 05/2019

Brand Name	Generic Name
NOXAFIL oral suspension	posaconazole

CRITERIA FOR COVERAGE/NONCOVERAGE

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 hematopoietic 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

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 03/2019.
2. Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com.Accessed 03/2019,

Non Formulary	
Brand Name	Generic Name
NUEDEXTA	dextromethorphan/quinidine

CRITERIA FOR COVERAGE/NON-COVERAGE

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:

1. Nuedexta prescribing information. Aliso Viejo, CA. Avanir Pharmaceuticals. Rev Jan 2015.
2. Pioro EP, Brooks BR, et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. *Ann Neurol*. 2010;68:693- 702.

3. Panitch HS, Thisted RA, et al. Randomized, controlled trial of dextromethorphan/quinidine for pseudobulbar affect in multiple sclerosis. *Ann Neurol*. 2006;59:780-787.
4. Brooks BE, Thisted RA, et al. Treatment of pseudobulbar affect in ALS with dextromethorphan/quinidine, a randomized trial. *Neurology*. 2004;63:1364-1370.
5. Minden SL, Feinstein A, et al. Evidence-based guideline: assessment and management of psychiatric disorders in individuals with MS. *American Academy of Neurology*. 2014;82:174-181.
6. Miller RG, Jackson CE, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Multidisciplinary care, symptomatic management, and cognitive/behavioral impairment (an evidence-based review). *Neurology*. 2009;73:1227-1233.
7. Pope LE, Hepner A, Kaye RE. Evaluation of the safety of dextromethorphan; quinidine for treatment of pseudobulbar affect in patients across a range of neurological conditions. Presented at 164th APA annual meeting. Honolulu, Hawaii; May 2011.
8. Cummings Jeffrey, et al. Pseudobulbar Affect. A disabling but under-recognised consequence of neurological disease and brain injury.
9. Patteel GL, et al. An open-label multicenter study to assess the safety of dextromethorphan/quinidine in patients with pseudobulbar affect associated with a range of underlying neurological conditions.

Research/clinical notes:

Miller RG, Jackson CE, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Multidisciplinary care, symptomatic management, and cognitive/behavioral impairment (an evidence-based review).

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.

Minden SL, Feinstein A, et al. Evidence-based guideline: assessment and management of psychiatric disorders in individuals with MS. American Academy of Neurology. 2014;82:174-181.

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-LS₁₈ 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.

NON FORMULARY	
Brand Name	Generic Name
OLUMIANT	baricitinib

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 \geq 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. 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. 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:

1. Olumiant prescribing information. Indianapolis, IN. Lilly USA, LLC. Rev May 2018.
2. Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2016 Jan;68(1):1-25.

Formulary Oral Oncology Agents – PA required			
Brand Name	Generic Name	Brand Name	Generic Name
AFINITOR	everolimus	PIQRAY	alpelisib
ARIMIDEX	anastrozole	REVLIMID	lenalidomide
AROMASIN	exemestane	SUTENT	sunitinib
CAPRESLA	vandetanib	TARGRETIN	bexarotene
CYTOXAN	cyclophosphamide	TARCEVA	erlotinib
ETOPOPHOS	etoposide	TASIGNA	nilotinib
GLEEVEC	imatinib	THALOMID	thalidomide
GLEOSTINE	lomustine	TURALIO	pexidartinib
IMBRUVICA	obrutinib	TYKERB	lapatinib
INLYTA	axitinib	VESANOID	tertinoin
IRESSA	gefitinib	VENCLEXTA	venetoclax
JAKAFI	ruxolitinib	VOTRIENT	pazopanib
LEUCOVORIN	leucovorin	XALKORI	crizotinib
MATULANE	procarbazine	ZELBORAF	vemurafenib
NEXAVAR	sorafenib	ZOLINZA	vorinostat
NUBEQA	darolutamide	ZYTIGA (250mg tablet only)	abiraterone
Iclusig	ponatinib	Tagrisso	osimertinib

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.
- iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an Evidence Level A and 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.
- b. Note- If a generic exists, and a request is for Brand product, the member must have an adequate trial and failure (or contraindication) to the generic product.
- c. Evidence of previous trial of 2 prior kinase inhibitors if request is for Iclusig for the diagnosis of CML.

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.
- b. If request is for generic Zytiga (abiraterone), only the 250mg tablet will be approved up to 1000mg daily (120 tablets per 30 days).

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.

Criteria Name
NON FORMULARY Oral Oncology Drugs

CRITERIA FOR COVERAGE/NONCOVERAGE
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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***.

- iv. Facts and Comparisons/Wolters Kluwer Lexi-Drugs with an ***Evidence Level A and 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 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 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:

1. Centers for Medicare & Medicaid Services. Compendia. Retrieved from: www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=6&mcdtypename=Compendia&bc=AgAAAAAAAAAAAA%3D%3D&
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. 2017.
3. American Society of Clinical Oncology (ASCO). ASCO Guidelines, Tools, & Resources. 2017.
4. Facts & Comparisons Answers. Available at: <http://online.factsandcomparisons.com> Accessed 7/2017.
5. Micromedex/DRUGDEX. Available at: www.micromedexsolutions.com Accessed 7/2017.
6. Arizona Health Care Cost Containment System. AHCCCS Medical Policy Manual. Policy 310-V Prescription Medications/Pharmacy Services. Rev 2/1/2017.

Non Formulary	
Brand Name	Generic Name
ORENCIA	abatacept

CRITERIA FOR COVERAGE/NON-COVERAGE

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

- Prescribed by or in consultation with a rheumatologist.
- Age ≥ 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or provider attestation.
- Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
 - Methotrexate
 - Hydroxychloroquine
 - Sulfasalazine
 - Leflunomide
- 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).
- 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 Health Choice****

References:

1. Oencia prescribing information. Princeton, NJ. Bristol-Myers Squibb Company. Rev Jun 2017.
2. Singh J, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.
3. Lovell DJ, Ruperto N, et al. Adalimumab with or without Methotrexate in Juvenile Rheumatoid Arthritis. *N Engl J Med*;359:810-820 Aug 2018.
4. Ringold S, Weiss P, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. *Arthritis & Rheumatism*. Vol 65(10);Oct 2013,2499-2512.
5. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.

Brand Name	Generic Name
ORILISSA	elagolix

CRITERIA FOR COVERAGE/NON-COVERAGE

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 two 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, Ashlyna,
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:

1. Orilissa prescribing information. North Chicago, IL. AbbVie Inc. Rev Jul 2018.
2. ICER Institute for Clinical and Economic Review. Elagolix for Treating Endometriosis. Final Evidence Report. August, 3, 2018.
3. Selak V, Farquhar C, et al. Danazol for pelvic pain associated with endometriosis. *Cochrane Database Syst Rev*. 2007.
4. Nawathe A, Patwardhan S, et al. Systematic review of the effects of aromatase inhibitors on pain associated with endometriosis. *BJOG*. 2008 Jun;115(7):818-22.
5. Walch K, Unfried G, et al. Implanon versus medroxyprogesterone acetate: Effects on pain scores in patient with symptomatic endometriosis – a pilot study. *Contraception*. 2009;79(1):29.
6. Yisa SB, Okenwa AA, et al. Treatment of pelvic endometriosis with etonogestrel subdermal implant (Implanon). *J Fam Plann Reprod Health Care*. 2005;31(1):67.
7. Schenken RS. Endometriosis: Treatment of pelvic pain. UpToDate. Waltham, MA. Updated Jun 2018.
8. American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

Brand Name	Generic Name
ORLADEYO	berotralstat
TAKHZYRO	lanadelumab-flyo

CRITERIA FOR COVERAGE/NONCOVERAGE
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Orladeyo is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older. Orladeyo is available as an oral capsule.

Takhzyro is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of HAE in patients 12 years and older. Takhzyro is available as a self-administered subcutaneous injection.

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

1. Prescribed by an immunologist or allergist.
2. Member is 12 years of age or older.
3. Documented diagnosis of Type 1 or Type II hereditary angioedema.
4. Laboratory documentation submitted of serum C4 and C1-INH (antigenic or functional level) that are below the limits of the laboratory's normal reference range.
5. Documentation of history of HAE attacks that are consistent with at least one of the following:
 - a. One or more abdominal or respiratory attacks per month.
 - b. History of recurrent laryngeal attacks.
 - c. Required emergency medical care three or more times per year.
5. Documentation submitted by chart notes, and by prescription claim history if applicable, that HAE triggers have been identified and are being appropriately treated and/or avoided.
6. Documentation of an insufficient response or contraindication to one medication* in both of the following classes of medications:
 - a. 17 α – 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
7. Documented adequate trial of at least 30 days with an “on-demand” HAE therapy product such as Firazyr (icatibant) with lack of satisfactory improvement in severity and frequency of HAE attacks.
8. *For Takhzyro* - Documented trial and clinical failure of or intolerance to Cinryze and Haegarda.
9. *For Orladeyo* - Documented trial and clinical failure of, or intolerance to Cinryze, Haegarda, and Takhzyro, or other supported rationale why these are not therapeutic options.

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

Quantity Limits:

- **Orladeyo:** 150mg orally once daily
- **Takhzyro:** initial dosage: 300 mg subQ every 2 weeks; may consider dosing once every 4 weeks when member is attack free for greater than 6 months.

Continuation criteria:

1. Documentation by chart notes, and by prescription claim history if applicable, that HAE triggers are continually being identified and confirmed, and are still 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 Orladeyo or Takhzyro.
3. Documentation submitted supporting reduction in the utilization of on-demand therapies used for acute attacks (Firazyr, Ruconest, Berinert, or Kalbitor).

Exclusions:

1. Concomitant dual therapy with other HAE preventative medications (Cinryze, Haegarda).

References:

1. Orladeyo prescribing information. Durham, NC. BioCryst Pharmaceuticals, Inc. Rev Dec 2020.
2. Takhzyro prescribing information. Lexington, MA. Dyax Corp. Rev Nov 2018.
3. Bowen T, Cicardi M, et al. 2010 International consensus algorithm for the diagnosis, therapy and management of hereditary angioedema. *Allergy Asthma Clin Immunol.* 2010;6(1):24.
4. Zuraw BL, Banerji A, Bernstein JA, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. *J Allergy Clin Immunol: In Practice.* 2013;1:458-467
5. Busse PJ, Christiansen SC, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. *J Allergy Clin Immunol Pract.* 2020 Sep 6:S2213-2198(20)30878-3.

Formulary PAH	
Brand Name	Generic Name
REVATIO	sildenafil
ADCIRCA	tadalafil
TRACLEER	bosentan
LETAIRIS	ambrisentan
REMODULIN	treprostinil

CRITERIA FOR COVERAGE/NON-COVERAGE

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.

		Indicated for PAH WHO Group 1	Indicated to improve exercise	Indicated for idiopathic or congenital PAH in pediatric (≥ 3 yr.old) patients
PDE5s	sildenafil	✓	✓	
	Adcirca	✓	✓	
ERAs	Tracleer	✓	✓	✓
	Letairis	✓	✓	

Prostacyclin analogs	Remodulin	✓	✓	
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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)
 - 1.1. 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:

1. Taichman D, Ornelas J, Chung L, et al. CHEST guideline and expert panel report: Pharmacologic therapy for pulmonary arterial hypertension in adults. *Chest*. 2014; 146(2):449-475.
2. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension, 2015. *Eur Heart J* Aug 2015.
3. Galie N, Corris P, et al. Updated Treatment Algorithm of Pulmonary Hypertension. *J Am Coll Cardiol* 2013;62(25), Suppl D.
4. Revatio prescribing information. New York, NY. Pfizer Labs. Rev Jul 2017.
5. Adcirca prescribing information. Indianapolis, IN. Eli Lilly and Company. Rev May 2017.
6. Tracleer prescribing information. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Rev Sep 2017.
7. Letairis prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev Oct 2015.
8. Tyvaso prescribing information. Research Triangle Park, NC. United Therapeutics Corp. Rev Oct 2017.
9. Ventavis prescribing information. South San Francisco. Actelion Pharmaceuticals US, Inc. Rev Jan 2008.
10. Flolan prescribing information. Research Triangle Park, NC. GlaxoSmithKline. Rev Jan 2008.
11. Remodulin prescribing information. Research Triangle Park, NC. United Therapeutic Corp. Rev Dec 2014.
12. McLaughlin VV, et al. ACCF/AHA 2009 Expert Consensus Document on Pulmonary Hypertension. A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association.

NONFORMULARY PAH	
Brand Name	Generic Name
OPSUMIT	macitentan
ADEMPAS	riociguat
UPTRAVI	selexipag
ORENITRAM	treprostinil tablets
TYVASO	treprostinil
VENTAVIS	iloprost
FLOLAN	epoprostenol

CRITERIA FOR COVERAGE/NON-COVERAGE

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 I 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.

Tyvaso and Ventavis are both prostacyclin analogs and indicated for the treatment of PAH WHO Group 1 to improve exercise ability. **Tyvaso** is also indicated for the treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) 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

- 2. 1. Tyvaso or Ventavis (for PAH Group 1): Documentation member is NYHA Class III-IV. Tyvaso only: documentation to treat pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability.

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).

Note: 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, Veletri), 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:

1. Adempas prescribing information. Whippany, NJ. Bayer HealthCare Pharmaceuticals, Inc. Rev Jan 2017.
2. Taichman D, Ornelas J, Chung L, et al. CHEST guideline and expert panel report: Pharmacologic therapy for pulmonary arterial hypertension in adults. *Chest*. 2014; 146 (2): 449-475.
3. Uptravi prescribing information. San Francisco. Actelion Pharmaceutical US, Inc. Rev Dec 2015.
4. Orenitram prescribing information. Research Triangle Park, NC. United Therapeutics Corp. Rev Jan 2017.
5. Opsumit [prescribing information. San Francisco, CA. Actelion Pharmaceuticals US, Inc. Rev Mar 2017.
6. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension, 2015. *Eur Heart J* 2015.

7. Galie N, Corris P, et al. Updated Treatment Algorithm of Pulmonary Hypertension. *J Am Coll Cardiol* 2013;62(25), Suppl D.

Brand Name	Generic Name
PEGASYS®	Peginterferon alfa-2a
PEGINTRON®	Peginterferon alfa-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

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 09/2016
2. Facts&ComparisonseAnswersat<http://online.factsandcomparisons.com>. Accessed 09/2016

Non-Formulary	
Brand Name	Generic Name
PEXEVA	Paroxetine mesylate

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:

1. Pexeva prescribing information. Roswell, GA. Sebela Pharmaceutical Inc. Rev Jan 2017.
2. Claghorn J. A double-blind comparison of paroxetine and placebo in the treatment of depressed outpatients. *Int Clin Psychopharmacol.* 1992;suppl 4:25-20.
3. Dunbar GC, Fuell DL. The anti-anxiety and anti-agitation effects of paroxetine in depressed patients. *Int Clin Psychopharmacol.* 1992;suppl 4:81-90.
4. Gelenberg AJ, Freeman MP. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. American Psychiatric Association. 2010.
5. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
6. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer.

Covered Product	Reference Brand Name
pimecrolimus	ELIDEL 1% CREAM

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 acetone 0.05% (Lidex) cream, ointment, gel, solution

triamcinolone acetone 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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 02/2019
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 02/2019
3. Elidel [Prescribing information] Bridgewater, NJ: Valeant Pharmaceuticals. 02/2019.
4. Boone B, Ongena K, van Geel N et al. Topical pimecrolimus in the treatment of vitiligo. *Eur J Dermatol* 2007; 17:5561.
5. Dawid M, Veensalu M, Grassberger M, Wolff K. et al, Efficacy and safety of pimecrolimus cream 1% in adult patients with vitiligo: Results of a randomized, double-blind, vehicle-controlled study. *Journal der Deutschen Dermatologischen Gesellschaft*. 2006;4:942-946
6. Coskun B, Saral Y, Turgut D. Topical 0.05% clobetasol propionate versus 1% pimecrolimus ointment in vitiligo. *Eur J Dermatol* 2005;15:8891
7. Grimes PE, Morris R, Avaniss-Aghajani E, et al. Topical tacrolimus therapy for vitiligo: therapeutic responses and skin messenger RNA expression of proinflammatory cytokines. *J Am Acad Dermatol*. 2004;51:52-61
8. Lepe V, Moncada B, Castaneda-Cazares JP, et al. A double-blind randomized trial of 0.1% tacrolimus vs. 0.05% clobetasol for the treatment of childhood vitiligo. *Arch Dermatol* 2003; 139:5815.

Non-Formulary PCSK 9 Agent - Brand Name (Generic)
PRALUENT (alirocumab)

CRITERIA FOR COVERAGE/NONCOVERAGE
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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 $> 290\text{mg/dL}$ or LDL cholesterol $> 190\text{mg/dL}$ 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
 - c. Diagnosis of **homozygous** familial hypercholesterolemia (HoFH) as confirmed by ONE of the following:
 - i. Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

- ii. Both of the following:
 - 1. Either untreated/pre-treatment LDL-C > 500 mg/dL or treated LDL-C > 300 mg/dL
 - 2. Xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents
- 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 $\leq 50\%$ 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) $\geq 80\%$
- 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) $\geq 80\%$

Authorization for Initial approval: 3 months and renewal approval: One year

Covered Product	Brand Name
Pregabalin	LYRICA

CRITERIA FOR COVERAGE/NONCOVERAGE

Quantity Limit: 2/28 days

References:

1. Praluent Prescribing Information. Bridgewater, New Jersey. Sanofi-Aventis, LLC. Revised April 2017. Accessed 6/2021. Available at: www.products.sanofi.us/praluent/praluent.pdf
2. Jacobson T, Ito M, Maki K, et al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1 – Full Report. J Clin Lipidol. 2015;9(2): 129-169. Available at: [http://www.lipidjournal.com/article/S1933-2874\(15\)00059-8/fulltext](http://www.lipidjournal.com/article/S1933-2874(15)00059-8/fulltext)
3. Lloyd-Jones DM, Morris PB, Ballantyne CM et al. 2016 Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol 2016;Apr 1. Available at: www.acc.org/latest-in-cardiology/ten-points-to-remember/2016/03/30/11/58/2016-acc-expert-consensus-decision-pathway-on-the-role-of-nonstatin
4. Stone N, Robinson J, Lichtenstein AH et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014;129(25 Suppl.2):S1–S45.
5. UpToDate. www.uptodate.com Accessed 6/2017
6. Micromedex/DRUGDEX at www.microdexsolutions.com Accessed 6/2017

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

- 1) Thirty (30) day trial of Gabapentin in the previous 90 days.

References

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
2. Facts& ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 11/2016

Brand Name	Generic Name
PREVYMIS	Letermovir

CRITERIA FOR COVERAGE/NON-COVERAGE

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

Brand Name	Generic Name
PROMACTA tablets, oral suspension	Eltrombopag

CRITERIA FOR COVERAGE/NONCOVERAGE

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/ μ L).
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:

- Neutrophils less than $0.5 \times 10^9/L$ (< 500 cells/ μL)
 - Platelets less than 20,000/ μL
 - Reticulocytes less than 1% corrected (percentage of actual hematocrit [Hct] to normal Hct) or reticulocyte count $< 20,000$ cells/ μL
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 ($< 30,000/\mu L$).
 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 $> 50,000/\mu L$ 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 $> 50,000/\mu L$ 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:

1. Promacta prescribing information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Jul 2018.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. *Blood*. 2011;117:4190-4207.
3. Neunert C, Despotovic J, et al, for the Pediatric ITP Consortium of North America (ICON). Thrombopoietin receptor agonist use in children: Data from the Pediatric ITP Consortium of North America ICON2 Study. *Pediatric Blood Cancer*. 2016;63(8):1407-1413.
4. Marsh JC, Ball SE, et al. Guidelines for the diagnosis and management of aplastic anaemia. *Br J Haematol*. 2009 Oct; 147(1):43-70. doi: 10.1111/j.1365- 2141.2009.07842.x. Epub 2009 Aug 10. 4.
5. Guinan EC. Diagnosis and management of aplastic anemia. *Hematology Am Soc Hematol Educ Program*. 2011; 2011:76-81. doi: 10.1182/asheducation-2011.1.76. Review
6. Killick SB, Bown N, et al. Guidelines for the diagnosis and management of adult aplastic anaemia. *Br J Haematol*. 2016;172:187–207.
7. George JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Initial treatment and prognosis. UpToDate. Waltham, MA. Updated Apr 2018.
8. George, JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. UpToDate. Waltham, MA. Updated Jun 2018.

Nonformulary	
Brand Name	Generic Name
PROZAC WEEKLY	fluoxetine delayed release capsules

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:

1. Prozac prescribing information. Indianapolis, IN. Lilly USA, LLC. Rev Mar 2017.
2. Schmidt ME, Fava M, et al. The Efficacy and Safety of a New Enteric-Coated Formulation of Fluoxetine Given Once Weekly During the Continuation Treatment of Major Depressive Disorder. *J Clin Psychiatry*. 2000;61(11):851-857.
3. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
4. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer.
5. Gelenberg AJ, Freeman MP. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. American Psychiatric Association. 2010.

Brand Name	Generic Name
PULMICORT RESPULES – Non Formulary	budesonide
Budesonide respules – Preferred product	

CRITERIA FOR COVERAGE/NON-COVERAGE

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

1. No review is required for members 4 years of age and under.
2. The member has a diagnosis of asthma.
3. 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.

References

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

NONFORMULARY	
Generic Name	Brand Name
Ramelteon	ROZEREM

CRITERIA FOR COVERAGE/NONCOVERAGE

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.
4. Member has a documented trial and failure to BRAND Rozerem (preferred agent)

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:

1. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;12(2):307-349.
2. Rozerem prescribing information Deerfield, IL. Takeda Pharmaceuticals America Inc. Rev 11/2010. Criteria revised 9/2017
3. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 04/2019

Nonformulary	
Brand Name	Generic Name
RANEXA®	ranolazine

CRITERIA FOR COVERAGE/NONCOVERAGE
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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.).

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:

1. Ranexa prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev 1/2016.
2. Amsterdam EA, Wenger NK, et al. 2014 AHA/ACC Guideline for the Management of Patients with Non–ST-Elevation Acute Coronary Syndromes. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*. Vol 64(24) Dec 2014.
3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 7/2017.
4. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 7/2017.

Covered Product	Brand Name
Ranolazine ER®	RANEXA

CRITERIA FOR COVERAGE/NONCOVERAGE
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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:

1. Ranexa prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev 1/2016.
2. Amsterdam EA, Wenger NK, et al. 2014 AHA/ACC Guideline for the Management of Patients with Non–ST-Elevation Acute Coronary Syndromes. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*. Vol 64(24) Dec 2014.
3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 7/2017.
4. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 7/2017.

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)
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REPATHA (evolocumab)

CRITERIA FOR COVERAGE/NONCOVERAGE
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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:
 - iii. Genetic confirmation of 2 mutant alleles at LDL receptor (LDLR), ApoB-100, PCSK9.
 - iv. 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 $\leq 50\%$ 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:

- 1. Repatha prescribing information. Thousand Oaks, CA. Amgen Inc. Revised 2/2019. Accessed 05/2019. Available at: www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/repatha/repatha_pi_hcp_english.ashx
- 2. Jacobson T, Ito M, Maki K, et al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1 – Full Report. J Clin Lipidol. 2015;9(2): 129-169. Available at: [http://www.lipidjournal.com/article/S1933-2874\(15\)00059-8/fulltext](http://www.lipidjournal.com/article/S1933-2874(15)00059-8/fulltext)
- 3. Lloyd-Jones DM, Morris PB, Ballantyne CM et al. 2016 Expert Consensus Decision Pathway on the Role of Non-Statins Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol 2016;Apr 1. Available at: www.acc.org/latest-in-cardiology/ten-points-to-remember/2016/03/30/11/58/2016-acc-expert-consensus-decision-pathway-on-the-role-of-nonstatin
- 4. Stone N, Robinson J, Lichtenstein AH et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014;129(25 Suppl.2):S1–S45.
- 5. UpToDate. www.uptodate.com Accessed 04/2019.
- 6. Micromedex/DRUGDEX at www.microdexsolutions.com Accessed 04/2019.

RESPIRATORY AGENTS	
Brand Name	Generic Name
XOLAIR - MEDICAL	Omalizumab
NUCALA	mepolizumab
CINQAIR - MEDICAL	reslizumab
FASRENA	benralizumab

CRITERIA FOR COVERAGE/NONCOVERAGE

IgE mediated agents

Xolair is an interleukin-5 antagonist monoclonal antibody indicated for:

- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.
- Chronic idiopathic urticarial in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Eosinophilic mediated agents

Fasenra and Nucala are interleukin-5 receptor monoclonal antibodies (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Cinqair is an interleukin-5 antagonist monoclonal antibody (IgG4 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype.

CINQAIR and XOLAIR are administered in-office by a provider. Coverage is available under the MEDICAL benefit.

When self-administered at home, NUCALA and FASRENA may be covered under the pharmacy benefit with the following criteria are met:

Benralizumab (Fasenra)

Member has a diagnosis of **severe asthma with an eosinophilic phenotype** and is 12 years and older and all of the following is met:

1. Benralizumab is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

2. Documentation submitted member has severe asthma and one of the following:
 - Two or more severe asthma exacerbations requiring courses of systemic corticosteroids (steroid burst) within the past 12 months.
 - One or more serious asthma exacerbations requiring visit to emergency room or urgent care, or requiring hospitalization or mechanical ventilation within the past 12 months.
3. Lab documentation of baseline (prior to treatment) blood eosinophil count that is > 150 cells/microliter in the past 3 months or > 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.
7. Dosing requested of benralizumab is every 4 weeks for the first 3 doses then once every 8 weeks thereafter.

mepolizumab (Nucala)

All of the above, in addition to trial/failure of Fasrena.

Continuation of therapy criteria

1. Documentation submitted 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: Member is not receiving combined concomitant treatment with Xolair, Nucala, Cinqair, Fasenra, and dupilumab (Dupixent).

References

1. Xolair prescribing information. East Hanover, NJ. Novartis Pharmaceuticals Corp. Rev Jun 2017.
2. Nucala prescribing information. Philadelphia, PA. GlaxoSmithKline LLC. Rev Feb 2017.
3. Cinqair prescribing information. Frazer, PA. Teva Respiratory, LLC. Rev Mar 2016.
4. Fasenra prescribing information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Rev Nov 2017.
5. Global initiative for asthma (GINA), National Heart, Lung and Blood Institute (NHLBI), World Health Organization (WHO). Global strategy for asthma management and prevention. Global Initiative for Asthma (GINA). Bethesda, MD: Global Initiative for Asthma (GINA), National Heart, Lung and Blood Institute (NHLBI); February 2002.

Brand Name	Generic Name
RESTASIS	cyclosporine

CRITERIA FOR COVERAGE/NONCOVERAGE
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*****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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 04/2019.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 04/2019.
3. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred practice pattern guidelines. Dry Eye Syndrome. American Academy of Ophthalmology; 2013. URL: www.aao.org/ppp.
4. Shtein, RM. Dry eyes. UpToDate. Waltham, MA.

Brand Name	Generic Name
RETACRIT	Epoetin alfa

CRITERIA FOR COVERAGE/NON-COVERAGE

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

4. 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 non-cardiac, 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

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

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

References

3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
4. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Covered Products
Ribavirin oral products

CRITERIA FOR COVERAGE/NONCOVERAGE
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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 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

3. Male: Willing to use contraceptive methods.

AND

4. Ribavirin is distributed/dispensed by a designated Specialty Pharmacy.

AND

Approval duration will vary dependent upon patient's genotype and treatment history.

References

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
2. Facts&Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Brand Name	Generic Name
RINVOQ	upadacitinib

CRITERIA FOR COVERAGE/NON-COVERAGE

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 \geq 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) \geq 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 \geq 3 consecutive months
 - b. If documented intolerance or known contraindication to methotrexate, then one of the following disease-modifying antirheumatic agent for \geq 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) ≤ 3.2 162
- 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

Covered products	Brand or generic Name
Rivastigmine oral capsule	EXELON
Rivastigmine oral solution	EXELON
Rivastigmine patch	EXELON

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:

1. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu>. Accessed 9/9/17.
2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: <http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/>. 9/9/17.
3. Exelon prescribing information. East Hanover, NJ. Novartis, Inc. Rev Nov 2016.
4. Exelon patch prescribing information. East Hanover, NJ. Novartis, Inc. Rev Nov 2016.
5. Doody RS, Stevens JC, et al. Practice parameter: Management of dementia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. May 2001 Vol 56, no 9;1154-1166.
6. Folstein MF, Folstein SE, et al. Mini-mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-198. www.dementiatoday.com/wp-content/uploads/2012/06/MiniMentalStateExamination.pdf.

Step Therapy	
Brand Name	Generic Name
ROZEREM	Ramelteon

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. 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:

1. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;12(2):307-349.
2. Rozerem prescribing information Deerfield, IL. Takeda Pharmaceuticals America Inc. Rev 11/2010.
3. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 04/2019

Criteria Name
Short Acting Opioid Therapy Exceeding a 5 Day Supply
Applies to all short acting opioids (formulary and non-formulary agents)

CRITERIA FOR COVERAGE/NONCOVERAGE
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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.
2. Arizona Opioid Prescribing Guidelines, November 2014. <http://www.azdhs.gov>
3. <http://www.azleg.gov/ars/36/02606.htm>

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

1. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>
2. Arizona Opioid Prescribing Guidelines, 2019. <https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf>

3. www.micromedexsolutions.com Accessed 7/2019
4. <http://eanswers.factsandcomparisons.com/index.aspx> Accessed 7/2019

Brand Name	Generic Name
SELZENTRY	Maraviroc

CRITERIA FOR COVERAGE/NONCOVERAGE
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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 weighs at least 2kg, regardless of age.
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:
Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 04/2017

Nonformulary	
Brand Name	Generic Name
SENSIPAR	Cinacalcet

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, sevelamer)
 - ii. A vitamin D analog (e.g. calcitriol, doxercalciferol)
 - 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
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

1. Micromedex/DRUGDEX at www.micromedexsolutions.com. Accessed 03/2017
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 03/2017

Brand Name	Generic Name
Jardiance	empagliflozin
Invokana	canagliflozin
Farxiga	dapagliflozin
Invokamet	
Synjardy	
Xigduo XR	

CRITERIA FOR COVERAGE/NONCOVERAGE
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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:

INVOKANA, JARDIANCE OR FARXIGA:

- The member has diagnosis of Type 2 Diabetes Mellitus (DMII) and established atherosclerotic cardiovascular disease (ASCVD), heart failure (HF) or chronic kidney disease (CKD) and:
 - 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 \geq 30-59 ml/min.
- The member has a diagnosis of Type 2 Diabetes Mellitus (DMII) and no cardiovascular disease and:
 - 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 \geq 45mL/min.

FARXIGA ONLY:

- The member has a diagnosis of one of the following:

- a) heart failure, NYHA class II-IV, and using to reduce the risk of cardiovascular death and hospitalization.
- b) the risk reduction of sustained estimated glomerular filtration rate decline, end stage kidney disease, cardiovascular death and hospitalization for heart failure, in adults with chronic kidney disease at risk of progression.
- 2. Documentation of reduced ejection fraction (EF) of less than or equal to 40%.
- 3. Documentation of concurrent use with other medications used for heart failure, which may include beta-blockers, diuretics, ACE inhibitor, ARB, angiotensin receptor-neprilysin inhibitor (ARNI) or mineralocorticoid receptor antagonist (MRA).
- 4. eGFR \geq 30 ml/min.

Initial approval duration: 6 months

Continuation Criteria:

- 1. **TYPE II DIABETES MELLITUS:** 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.
- 2. **HEART FAILURE:**
 - a. Member has had improvement/stability of symptoms.
 - b. Reduced incidence of CV death & fewer hospitalizations/urgent care visits for heart failure.

Continuation approval duration: 12 months

Exclusion:

- Pre-diabetic patients (e.g., HbA1c \geq 5.7% **and** FPG \geq 100 mg/dL and $<$ 126 mg/dL (7.0 mmol/L) OR HbA1c $<$ 5.7%).
- FOR HEART FAILURE:
 - Symptomatic bradycardia or second/third degree heart block
 - Symptomatic hypotension or systolic BP less than 95 mmHg
 - Acute decompensated heart failure or hospitalization due to decompensated heart failure in the past 4 weeks.
 - MI, unstable angina, stroke, TIA, coronary revascularization, valvular repair/replacement, implantation of CRT in the past 12 weeks

References:

- 1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 10/2019
- 2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 10/2019
- 3. American Diabetes Association Standards of Medical Care in Diabetes – 2018. *Diabetes Care*. Jan 2019; 42 (Suppl. 1). Accessed at: https://care.diabetesjournals.org/content/42/Supplement_1. 10/2019.

4. AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm 2019. *Endocr Pract.* 2019. Accessed at: <https://www.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatment-algorithms/comprehensive>. 10/2019.
5. Nauck MA, Kahle M, Baranov O. Addition of a dipeptidyl peptidase-4 inhibitor, sitagliptin, to ongoing therapy with the glucagon-like peptide-1 receptor agonist liraglutide: A randomized controlled trial in patients with type 2 diabetes. *Diabetes Obes Metab.* 2017 Feb; 19 (2):200-207. doi: 10.1111/dom.12802. Epub 2016 Nov 9.
7. European society of cardiology guidelines (ESC)/European association for the study of diabetes (EASD)-2019. *European Heart Journal.* Aug 31, 2019. Accessed at: <https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehz486/5556890>
6. Busch RS, Kane MP. Combination SGLT2 inhibitor and GLP-1 receptor agonist therapy: a complementary approach to the treatment of type 2 diabetes. *Postgrad Med.* 2017 Sep; 129 (7):686-697. doi: 10.1080/00325481.2017.1342509. Epub 2017 Jun 28
7. DeFronzo RA. Combination therapy with GLP-1 receptor agonist and SGLT2 inhibitor. *Diabetes Obes Metab.* 2017 Oct; 19(10):1353-1362. doi: 10.1111/dom.12982. Epub 2017 Jun 7.
8. Farxiga prescribing information. Wilmington, DE. AstraZeneca Pharmaceuticals LP.

Brand Name	Generic Name
SIGNIFOR	pasireotide

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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Nonformulary	
Brand Name	Generic Name
SILENOR	Doxepin

CRITERIA FOR COVERAGE/NONCOVERAGE
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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:

1. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2017;12(2):307-349.
2. Silenor prescribing information. Morristown, NJ. Pernix Therapeutics. Accessed 04/2019.

Non Formulary	
Brand Name	Generic Name
SILIQ	brodalumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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 \geq 18 years.
- c. Documentation submitted member has no latent or active tuberculosis infection.
- d. Documented diagnosis of **moderate to severe** plaque psoriasis with \geq 10% of body surface area (BSA) affected.

Note: An exception to the \geq 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:
 - vi. Methotrexate oral tablets
 - vii. 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 Health Choice****

References:

1. Siliq prescribing information. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Rev Feb 2017.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.

NON FORMULARY	
Brand Name	Generic Name
SIMPONI	golimumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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

*****NOTE: Only Simponi for self-administration (SQ) is eligible for coverage under the Pharmacy benefit. Simponi Aria must be billed via Medical and requires Jcode review by the Plan Medical department.*****

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 \geq 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 \geq 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

- 3. Back pain
- 4. 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 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:

1. Simponi prescribing information. Horsham, PA. Janssen Biotech, Inc. Rev May 2018.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.
4. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010.
5. Ward MM, Deodhar A, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology*. 2015.
6. Van der Heijde D, Ramiro S, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Annals of the Rheumatic Diseases*. 2017;76:978-991.
7. Singh J, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.

Brand Name	Generic Name
SIVEXTRO	tedizolid phosphate

CRITERIA FOR COVERAGE/NONCOVERAGE
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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:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016
3. SIVEXTRO prescribing information. Cubist Pharmaceuticals, Inc. Lexington, MA. June 2014.
4. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. Clin Infect Dis. 2014;59(2):e10-52.

Criteria Name	
Spravato (esketamine) Nasal Spray	Prior Authorization Required

CRITERIA FOR COVERAGE/NONCOVERAGE
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Product Name: Spravato Nasal Spray	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Member has a confirmed diagnosis of major depressive disorder as defined by the DSM-V criteria and is treatment resistant.</p> <p style="text-align: center;">AND</p> <p>2 - Member is 18 years of age or older.</p> <p style="text-align: center;">AND</p> <p>3 - Spravato is prescribed by or in consultation with a psychiatric provider.</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p style="padding-left: 20px;">4.1 Member does not have an active substance use disorder (SUD)</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">4.2 Both of the following:</p> <ul style="list-style-type: none"> • Member has an active substance use disorder 	

- Member is currently receiving treatment

AND

5 - One of the following:

5.1 Member has experienced an inadequate response during the current depressive episode with each of the following therapies:

5.1.1 Two antidepressants from at least two different classes (must include one of each AHCCCS preferred agents: SSRI, SNRI, or bupropion) having different mechanisms of action at the maximally tolerated labeled dose, each used for at least 4-6 weeks

AND

5.1.2 At least two augmentation therapies below for at least 4 weeks:

- SSRI or SNRI, and a second-generation antipsychotic used concomitantly (aripiprazole, quetiapine, risperidone, olanzapine)
- SSRI or SNRI, and lithium used concomitantly
- SSRI or SNRI, and liothyronine (T3) used concomitantly
- SSRI or SNRI, and mirtazapine
- SSRI and bupropion and buspirone

OR

5.2 Member has active suicidal ideation and urgent symptom control is necessary

AND

6 - Esketamine is used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)

AND

7 - Esketamine is administered under the direct supervision of a healthcare provider

AND

8 - Provider is certified in the Spravato REMS program

AND

9 - Member must be monitored by a health care provider for at least 2 hours after administration.

Notes

Quantity Limit: For induction phase (weeks 1-4): 24 devices/month, For maintenance phase: 12 devices/month

Product Name: Spravato Nasal Spray

Approval Length

6 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Provider attests that the member has documented improvement or sustained improvement in depressive symptoms from baseline.

AND

2 - Member use of esketamine is in combination with an oral antidepressant.

AND

3 - Member administers esketamine under the direct supervision of a healthcare provider

AND

4 - Provider is certified in the Spravato REMS Program

AND

5 - Member must continue to be monitored by a health care provider certified by the Spravato REMS Program for at least 2 hours after administration.

Notes

Quantity Limit: For induction phase (weeks 1-4): 24 devices/month, For maintenance phase: 12 devices/month

Quantity Limits and Exclusions:

- Maximum dose of Spravato is 84 mg intranasally twice per week during the induction phase, (weeks 1-4); 84 mg intranasally once per week during the maintenance phase, weeks 5-8. During week 9 and thereafter, administer 56mg or 84mg every two weeks or once weekly.
- Spravato is available as a nasal spray containing 28 mg of esketamine per device. Each nasal spray device delivers two sprays containing a total of 28 mg esketamine.
- Esketamine will be considered experimental and investigational for all other indications.

Spravato is available only through a restricted program called the SPRAVATO REMS. Important requirements of the SPRAVATO REMS include the following:

- Pharmacies must be certified in the REMS and must only dispense Spravato to healthcare providers and settings that are certified for the REMS Program and to the provider's address that is listed on the provider's certification. Further information, including a list of certified pharmacies is available at www.SPRAVATOREMS.com or 1-855-382-6022.
- SPRAVATO as part of the REMS Program, must be dispensed to a certified Health Care Setting operating under a DEA number for the overall management and storage elements related to a controlled substance. When a healthcare setting is registered, they must designate an authorized representative to be responsible for ensuring compliance with all REMS requirements.
- Each provider who prescribes and oversees SPRAVATO administration must have a DEA number.
- A provider can enroll his/her own DEA # as a Healthcare setting as long as the location/address of the physician's DEA registration is the same as the Healthcare Setting where SPRAVATO will be administered.
- Healthcare practitioners must be certified in the program and ensure that Spravato is: 1) Only dispensed in healthcare settings to patients who are enrolled in the Spravato REMS Program. 2) Administered by patients under the direct observation of a healthcare

provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of Spravato.

Brand Name	Generic Name
STELARA	ustekinumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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)**

- Prescribed by or in consultation with a dermatologist.
- Age \geq 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of **moderate to severe** plaque psoriasis with \geq 10% of body surface area (BSA) affected.

Note: An exception to the \geq 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.

- 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. 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 \geq 12 years.
- c. Documentation submitted member has no latent or active tuberculosis infection.
- d. Documented diagnosis of **moderate to severe** plaque psoriasis with \geq 10% of body surface area (BSA) affected.
 - Note:** An exception to the \geq 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 (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. 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 \geq 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 Health Choice****

References:

1. Stelara prescribing information. Horsham, PA. Janssen Biotech, Inc. Rev Jun 2018.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.
4. Lichtenstein GR, Loftus EV, et al. ACG Clinical Guidelines: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018 Apr;113(4):481-517.

STEP THERAPY COVERAGE POLICY

Drug Class	Targeted Drugs	Requirement
BRONCHODILATOR AGENTS	ADVAIR, DULERA, AND SYMBICORT	Trial of one steroid inhaler: budesonide (Pulmicort) Flexhaler, Pulmicort Respules, Flovent HFA, Asmanex, Qvar Redihaler, or Alvesco
URINARY ANTISPASMODICS	DETROL, TOVIAZ	Trial of oxybutynin
Sleep Disorder Agents	ROZEREM	Trial of temazepam and zolpidem
Ezetimibe	Ezetimibe	Trial of a statin (30 days)
Pregabalin	Pregabalin	Trial of gabapentin (30 days)

Criteria Name
Stimate

CRITERIA FOR COVERAGE/NONCOVERAGE
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Member must meet following for initial approval:

- Diagnosis of Hemophilia A with factor VIII levels greater than 5%

OR

- Diagnosis of von Willebrand's disease (Type I) with factor VIII levels greater than 5%

(Note: If Stimate is requested for in office use prior authorization must be submitted thru medical benefit)

Initial approval duration: 12 months.

Approval quantity: When using the nasal spray it is important to use the product intended for hemostatic therapy (Stimate) rather than the product for enuresis, since the dose is higher for bleeding disorders (1.5 mg/mL rather than 0.01 percent). Give one puff (150 mcg in one nostril) in patients weighing <50 kg and two puffs (150 mcg in both nostrils) in patients weighing ≥50 kg.

Member must meet following for re-authorization approval:

- Member is showing positive response to Stimate.

Re-authorization approval duration: 12 months.

References:

1. Stimate Nasal Spray [Prescribing information] King of Prussia, PA: CSL Behring LLC; 2011
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically. Accessed March 2020.

Brand Name	Generic Name
SUBLOCADE	buprenorphine extended-release injection

CRITERIA FOR COVERAGE/NONCOVERAGE

Sublocade is a drug-device combination product for subcutaneous injection only. It is available in a pre-filled syringe and must be injected by a health care professional as per the FDA label. It is not available in retail pharmacies. Sublocade must be prescribed and dispensed as part of a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the product is not distributed directly to patients.

Sublocade is FDA approved to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who have received an oral transmucosal (used under the tongue or inside the cheek) buprenorphine-containing medicine at a dose that controls withdrawal symptoms for at least 7 days. It is designed to deliver sustained therapeutic plasma levels of buprenorphine at a controlled rate over a one month period. Sublocade has been classified as a CIII controlled substance.

Sublocade should be used as part of a complete treatment program that includes counseling and psychosocial support.

Buprenorphine hydrochloride is an opioid partial agonist at the mu-opioid receptor and an antagonist at the kappa opioid receptor, thus it exhibits a ceiling to its effects. The danger of overdose, abuse liability, and toxicity may be less than with full opioid agonists.

The safety and efficacy of Sublocade were evaluated in two clinical studies (one randomized controlled clinical trial and one open-label clinical trial) of 848 adults with a diagnosis of moderate-to-severe OUD who began treatment with buprenorphine/naloxone sublingual film (absorbed under the tongue). Once the dose was determined stable, patients were given Sublocade by injection. A response to MAT was measured by urine drug screening and self-reporting of illicit opioid use during the six-month treatment period. Results indicated that Sublocade-treated patients had more weeks without positive urine tests or self-reports of opioid use, and a higher proportion of patients had no evidence of illicit opioid use throughout the treatment period, compared to the placebo group.

The safety and efficacy of Sublocade have not been established in children or adolescents less than 17 years of age. Clinical studies of Sublocade did not include participants over the age of 65.

Health Choice considers the use of Sublocade medically necessary when all of the following below is met. Health Choice may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

INITIAL CRITERIA:

1. Documented diagnosis of moderate to severe opioid use disorder.

2. Documentation member has co-occurring serious mental illness and has a demonstrated history of non-adherence to oral medications.
3. Documentation member is currently maintained on 8mg to 24mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection.
4. Documentation member has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine.
5. Documentation member is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program.
6. Prescriber meets DATA 2000 requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X).
7. Documentation the prescriber has checked the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to initial injection.
8. Requested Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: 300mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg or 300mg monthly.

APPROVAL LENGTH – 6 MONTHS

REAUTHORIZATION CRITERIA:

1. Documentation by physician that the member has experienced a positive clinical response to buprenorphine extended-release therapy, as defined by the provider.
2. Documentation supporting the member has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine.
3. Documentation the member is continuing to receive psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program.
4. Prescriber continues to meet DATA 2000 requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X). *[See Appendix 1 for more information]*
5. Documentation the prescriber continues to check the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection.
7. Requested Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: 300mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg or 300mg monthly.

APPROVAL LENGTH – 12 months

Limitations and Exclusions

Approval authorization will not be granted if any of the following conditions listed below apply. Health choice has determined the following use is unproven and not medically necessary.

1. Requested use for pain management.

References

1. Sublocade prescribing information. North Chesterfield, VA. Indivior Inc. Rev Oct 2019.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209819s000lbl.pdf
2. AHCCCS Medical Policy Manual (AMPM), Chapter 300, Medical Policy for Covered Services.
www.azahcccs.gov. Accessed Oct 2019.
3. Buprenorphine Treatment Physician Locator. Retrieved Oct 28, 2019 from
www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator
4. Haight BR, Learned SM, Laffont CM, et al. Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2019 Feb 23;393(10173):778-790.
5. U.S. Food and Drug Administration (FDA). FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder. Silver Spring, MD: FDA; November 30, 2017. Available at:

www.fda.gov/news-events/press-announcements/fda-approves-first-once-monthly-buprenorphine-injection-medication-assisted-treatment-option-opioid

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 $\mu\text{mol}/\text{min}/\text{g}$ 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-isomaltase (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.
2. Treem WR, McAdams L, et al. Sacrosidase therapy for congenital sucrase-isomaltase deficiency. *J Pediatr Gastroenterol Nutr.* 1999 Feb;28(2):137-42.
3. National Organization for Rare Disorders (NORD). Disaccharide Intolerance I. Available at: <https://rarediseases.org/rare-diseases/disaccharide-intolerance-i/>.

Covered Product	Reference Brand Name
Tacrolimus Ointment (0.03% & 0.1%)	PROTOPIC

CRITERIA FOR COVERAGE/NONCOVERAGE

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

halobetasol propionate 0.05% (Ultravate) cream, ointment

High Potency:

augmented betamethasone 0.05% (Diprolene) cream

diflorasone 0.05% (Psorcone E, Florone) cream, ointment

fluocinonide acetone 0.05% (Lidex) cream, ointment, gel, solution

triamcinolone acetone 0.5% (Aristocort, Kenalog) cream, ointment

Medium Potency:

desoximetasone 0.05% (Topicort) cream, ointment, gel

fluocinolone acetone 0.025% (Synalar) cream, ointment

mometasone 0.1% (Elocon) cream, ointment, lotion

triamcinolone acetone 0.025%, 0.1% (Aristocort, Kenalog) cream, ointment

Low Potency:

aclofetasone 0.05% (Aclovate) cream, ointment

desonide 0.05% (Desowen) cream, ointment, lotion

fluocinolone acetone 0.01% (Synalar) solution

hydrocortisone 2.5% (Hytone) cream, ointment

References:

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 02/2019
2. Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 02/2019
3. Boone B, Ongena K, van Geel N et al. Topical pimecrolimus in the treatment of vitiligo. Eur J Dermatol 2007; 17:5561.
4. Dawid M, Veensalu M, Grassberger M, Wolff K. et al, Efficacy and safety of pimecrolimus cream 1% in adult patients with vitiligo: Results of a randomized, double-blind, vehicle-controlled study. Journal der Deutschen Dermatologischen Gesellschaft. 2006;4:942-946
5. Coskun B, Saral Y, Turgut D. Topical 0.05% clobetasol propionate versus 1% pimecrolimus ointment in vitiligo. Eur J Dermatol 2005;15:8891
6. Grimes PE, Morris R, Avaniss-Aghajani E, et al. Topical tacrolimus therapy for vitiligo: therapeutic responses and skin messenger RNA expression of proinflammatory cytokines. J Am Acad Dermatol. 2004;51:52-61
7. Lepe V, Moncada B, Castaneda-Cazares JP, et al. A double-blind randomized trial of 0.1% tacrolimus vs. 0.05% clobetasol for the treatment of childhood vitiligo. Arch Dermatol 2003; 139:5815.

NON FORMULARY	
Brand Name	Generic Name
TALTZ	ixekizumab

CRITERIA FOR COVERAGE/NON-COVERAGE

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
- Ankylosing spondylitis
- Non-radiographic axial spondyloarthritis with objective signs of inflammation

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

1. Plaque Psoriasis (Adult)

- Prescribed by or in consultation with a dermatologist.
- Age ≥ 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of **moderate to severe** plaque psoriasis with $\geq 10\%$ of body surface area (BSA) affected.

Note: An exception to the $\geq 10\%$ 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.

- 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:

- Calcipotriene (generic for Dovonex) topical preparations
- 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.

- Tacrolimus 0.1% (prior authorization required) ointment
- Coal tar preparations such as coal tar shampoo

- 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 \geq 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.

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 Taltz will be self-administered by the member at a maintenance dose of 80 mg and dosing interval of no less than every 4 weeks.

4. Non-radiographic axial spondyloarthritis, Active; with objective signs of inflammation

- 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 Taltz will be self-administered by the member at a maintenance dose of 80 mg and dosing interval of no less than every 4 weeks

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.

Ankylosing Spondylitis – Two syringes the first month, then one syringe a month thereafter

Axial spondyloarthritis –One syringe a month

Continuation Criteria:

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 Health Choice****

References:

1. Taltz prescribing information. Indianapolis, IN. Eli Lilly and Co. Rev May 2018.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.

3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.

Non Formulary	
Brand Name	Generic Name
TAVALISSE	fostamatinib
DOPTELET	avatrombopag

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 ($< 30,000/\mu\text{L}$).
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

Platelet Count ($\times 10^9/\text{L}$)	Once Daily Dose	Duration
Less than 40	60 mg (3 tablets)	5 days
40 to less than 50	40 mg (2 tablets)	5 days

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:

1. Tavalisse prescribing information. South San Francisco, CA. Rigel Pharmaceuticals, Inc. Rev Apr 2018.
2. Doptelet prescribing information. Durham, NC. Dova Pharmaceuticals. Rev May 2018.
3. George JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Initial treatment and prognosis. UpToDate. Waltham, MA. Updated Apr 2018.
4. George, JN, Arnold DM. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. UpToDate. Waltham, MA. Updated Jun 2018.

Products	Generic/brand name
testosterone injection (cypionate or enanthate)	Depo-testosterone/Delatestryl
testosterone topical 1%, 1.62% gel (pkts and pump)	Androgel 1%
testosterone topical solution	Axiron
ANDRODERM PATCH	testosterone

CRITERIA FOR COVERAGE/NONCOVERAGE
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*****Effective 4/1/2021, Brand Androgel is preferred topical agent. All other topical agents are non-formulary. Testosterone Injection remains formulary w/PA*****

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:

- 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 apart 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
- 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 (hypogonadotropic hypogonadism).⁵ 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.⁵*

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.⁵*

Exclusions for male testosterone replacement therapy:

- 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

>10years 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:

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 06/2019.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 06/2019.
3. PubMed Article: <http://www.ncbi.nlm.nih.gov/> Accessed 09/2016.
4. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. Jun;95(6):2536-59.
5. Petak, SM. American Association of Clinical Endocrinologists medical Guidelines for the Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update. *Endocrine Practice*. Vol 8 No. 6 Nov/Dec 2002.
6. FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use. Available at: www.fda.gov/Drugs/DrugSafety/ucm436259.htm. Mar 2015.
7. Depo-Testosterone prescribing information. New York, NY. Pharmacia & Upjohn Co. Rev 10/2016.
8. Delatestryl prescribing information. Malvern, PA. Endo Pharmaceuticals. Rev 10/2016.
9. American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders: DSM-5. Washington, D.C: American Psychiatric Association.

Brand Name	Generic Name
TRAVATAN Z	travoprost 0.004%

CRITERIA FOR COVERAGE/NONCOVERAGE
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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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 04/2019
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 04/2019

Non Formulary	
Brand Name	Generic Name
TREMFYA	goselkumab

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.

TREMFYA 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 \geq 18 years.
- c. Documentation submitted member has no latent or active tuberculosis infection.
- d. Documented diagnosis of **moderate to severe** plaque psoriasis with \geq 10% of body surface area (BSA) affected.

Note: An exception to the \geq 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. 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 Health Choice****

References:

1. Tremfya prescribing information. Horsham, PA. Janssen Biotech, Inc. Rev Oct 2017.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.

Non-Formulary Product	Formulary Brand Name
tretinoin cream (0.025%, 0.05%, 0.1%) tretinoin gel (0.01%, 0.025%, 0.05%)	Retin-A

CRITERIA FOR COVERAGE/NONCOVERAGE
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Retin-A/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, Brand Retin-A is available without a prior authorization.**

Brand Retin-A is covered for patients who are 26 years of age or older and meet the following criteria:

1. Documented diagnosis of acne vulgaris.

Generic Tretinoin is covered for 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 Brand Retin-A

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:

1. Micromedex/DRUGDEX at www.microdexsolutions.com.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>.
3. <https://www.aad.org/practicecenter/quality/clinical-guidelines/acne>

Nonformulary	
Brand Name	Generic Name
ULORIC	febuxostat
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 reactions
 - 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:

1. Uloric prescribing information. Deerfield, IL. Takeda Pharmaceuticals America, Inc. Rev Feb 2018.

2. Khanna D, Fitzgerald JD, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 1: Systematic Nonpharmacologic and Pharmacologic Therapeutic Approaches to Hyperuricemia. *Arthritis Care & Research*. 2012; 64(10): 1431-1446).

Brand Name	Generic Name
VASCEPA (Non-Formulary)	Icosapent Ethyl

CRITERIA FOR COVERAGE/NONCOVERAGE

Vascepa is indicated:

- As adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and:
 - Established cardiovascular disease (CVD) or
 - Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia

Limitation(s) of use: The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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

I. Initial Approval Criteria

A. Hypertriglyceridemia without ASCVD (must meet all):

1. Diagnosis of hypertriglyceridemia;
2. Age ≥ 18 years;
3. Fasting triglycerides ≥ 500 mg/dL (lab must be dated within 90 days);
4. Failure of a ≥ 3 consecutive month trial of fibrate therapy in the last 6 months at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of omega-3-acid ethyl esters (generic Lovaza®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 4 g (4 capsules) per day.

Approval duration: 6 months

B. Reduction of Cardiovascular Disease Risk (must meet all):

1. Diagnosis of one of the following (a or b):
 - a) Atherosclerotic cardiovascular disease (ASCVD) as evidenced by a history of any one of the following conditions (i-vii);
 - i. Acute coronary syndromes;

- ii. Clinically significant coronary heart disease (CHD) diagnosed by invasive or noninvasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging);
 - iii. Coronary or other arterial revascularization;
 - iv. Myocardial infarction;
 - v. Peripheral arterial disease presumed to be of atherosclerotic origin;
 - vi. Stable or unstable angina;
 - vii. Stroke or transient ischemic attack (TIA);
- b) Diabetes with ≥ 2 CVD risk factors (see Appendix F);
- 2. Age ≥ 45 years;
- 3. Documentation (labs must be dated within 90 days) of fasting triglycerides between 150-499 mg/dL;
- 4. Documentation of low-density lipoprotein cholesterol (LDL-C) (labs must be dated within 90 days) between 41-100 mg/dL;
- 5. For members on statin therapy, both of the following (a and b):
 - a. Vascepa is prescribed in conjunction with a statin at the maximally tolerated dose;
 - b. Member has been adherent for at least the last 4 months to maximally tolerated doses of one of the following statin regimens (i, ii, or iii):
 - i. A high intensity statin;
 - ii. A moderate intensity statin and member has one of the following (a or b):
 - a) Intolerance to two high intensity statins;
 - b) A statin risk factor (see Appendix D);
 - iii. A low intensity statin and member has one of the following (a or b):
 - a) Intolerance to one high and one moderate intensity statins;
 - b) A statin risk factor (see Appendix D) and history of intolerance to two moderate intensity statins;
- 6. For members not on statin therapy, member meets one of the following (a or b):
 - a. Statin therapy is contraindicated per Appendix E;
 - b. For members who are statin intolerant, member has tried at least two statins, 1 of which must be a hydrophilic statin (pravastatin, fluvastatin, or rosuvastatin), and member meets one of the following (i or ii):
 - i. Member has documented statin risk factors (see Appendix D);
 - ii. Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b):
 - a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin rechallenge;
 - b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);
- 7. Dose does not exceed 4 g (4 capsules) per day.

Approval duration: 6 months

II. Continued Therapy

A. Hypertriglyceridemia without ASCVD (must meet all):

1. Currently receiving medication or member has previously met initial approval criteria;

2. Member is responding positively to therapy as evidenced by one of the following (a or b):
 - a. Initial re-authorization: 20% reduction in TG levels from baseline;
 - b. Subsequent re-authorizations: continued reduction or maintenance in reduction of TG levels from baseline;
3. If request is for a dose increase, new dose does not exceed 4 g (4 capsules) per day.

Approval duration: 12 months

B. Reduction of Cardiovascular Disease Risk (must meet all):

1. Currently receiving medication or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by no increase in TG and LDL-C levels from baseline;
3. If statin tolerant, documentation of adherence to a statin at the maximally tolerated dose;
4. If request is for a dose increase, new dose does not exceed 4 g (4 capsules) per day.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less)

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ASCVD: atherosclerotic cardiovascular disease

CVD: cardiovascular disease

EPA: eicosapentaenoic acid

FDA: Food and Drug Administration

LDL-C: low-density lipoprotein cholesterol

SAMS: statin-associated muscle symptoms

TG: triglyceride

Appendix B: Therapeutic Alternatives This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization

Drug Name	Dosing Regimen	Dosing Limit/ Maximum Dose
fenofibrate (TriCor®)	HyperTG without ASCVD: 48-145mg PO QD	145 mg/day
gemfibrozil (Lopid®)	HyperTG without ASCVD: 600 mg PO BID	1,200 mg/day
omega-3-acid ethyl esters (Lovaza®)	HyperTG without ASCVD: 4 g PO QD or 2 g PO BID	4 g/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components

- Boxed warning(s): none reported

Appendix D: *Statin Risk Factors*

- Multiple or serious comorbidities, including impaired renal or hepatic function
- Unexplained alanine transaminase (ALT) elevations > 3 times upper limit of normal, or active liver disease
- Concomitant use of drugs adversely affecting statin metabolism
- Age > 75 years, or history of hemorrhagic stroke
- Asian ancestry

Appendix E: *Statin Contraindications*

- Decompensated liver disease (development of jaundice, ascites, variceal bleeding, encephalopathy)
- Laboratory-confirmed acute liver injury or rhabdomyolysis resulting from statin treatment
- Pregnancy, actively trying to become pregnant, or nursing
- Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins

Appendix F: *Risk Factors for CVD (2019 ADA and 2013 AHA Guidelines)*

- Men and women ≥ 50 years of age
- Cigarette smoker or stopped smoking within 3 months
- Hypertension (blood pressure ≥ 140 mmHg systolic OR ≥ 90 mmHg diastolic) or on antihypertensive medication
- HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women
- Renal dysfunction: creatinine clearance (CrCL) > 30 and < 60 mL/min
- Micro- or macroalbuminuria. Microalbuminuria is defined as either a positive micral or other strip test (may be obtained from medical records), an albumin/creatinine ratio ≥ 2.5 mg/mmol or an albumin excretion rate on timed collection ≥ 20 mg/min all on at least two successive occasions; macroalbuminuria, defined as Albustix or other dipstick evidence of gross proteinuria, an albumin/creatinine ratio ≥ 25 mg/mmol or an albumin excretion rate on timed collection ≥ 200 mg/min all on at least two successive occasions
- Obesity/overweight
- Dyslipidemia
- Family history of premature coronary disease

Appendix G: *General Information*

- The diagnosis of SAMS is often made based on clinical criteria. Typical SAMS include muscle pain and aching (myalgia), cramps, and weakness. Symptoms are usually bilateral and involve large muscle groups, including the thigh, buttock, back, and shoulder girdle musculature. In contrast, cramping is usually unilateral and may involve small muscles of the hands and feet. Symptoms may be more frequent in physically active patients. Symptoms often appear early after starting statin therapy or after an increase in dose and usually resolve or start to dissipate within weeks after cessation of therapy, although it may take several months for symptoms to resolve completely. Persistence of symptoms for

more than 2 months after drug cessation should prompt a search for other causes or for underlying muscle disease possibly provoked by statin therapy. The reappearance of symptoms with statin rechallenge and their disappearance with drug cessation offers the best evidence that the symptoms are truly SAMS.

- Pravastatin, fluvastatin, and rosuvastatin are hydrophilic statins which have been reported to confer fewer adverse drug reactions than lipophilic statins.

Dosing and Administration

Indication	Dosing Regimen	Maximum Dose
Hypertriglyceridemia without ASCVD	2 g PO BID	4 g/day
Reduction of CVD risk		

References:

1. Vascepa Prescribing Information. Bedminster, NJ: Amarin Pharma, Inc.; December 2019. Available at: www.vascepa.com. Accessed December 27, 2019.
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APHA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2018;Nov 10:[Epub ahead of print].
3. Miller M, Stone NJ, Ballantyne C, et al. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation*. 2011; 123: 2292-2333.
4. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract* 2017;23(Suppl 2):1-87.
5. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2012;97(9):2969-2989.
6. Bhatt DL, Steg G, Miller M, et al. Cardiovascular risk reduction with icosapent ethyl for hypertriglyceridemia. *N Engl J Med*. 2019 Jan 1;380(1):11-22.
7. Skulas-Ray AC, Wilson PWF, Harris WS, et al. Omega-3 fatty acids for the management of hypertriglyceridemia: a science advisory from the American Heart Association. *Circulation*. 2019 Sep 17;140(12):e673-e691.
8. Manpuya WM, Cho L, Frid D, et al. Treatment strategies in patients with statin intolerance: the Cleveland Clinic experience. *American Heart Journal* 2013; 166(3):597-603.
9. Zhang H, Plutzky J, Skentzos S, et al. Discontinuation of statins in routine care settings. *Ann of Intern Med* 2013; 158(7):526-534.
10. Backes JM, Ruisinger JF, Gibson CA, et al. Statin-associated muscle symptoms—managing the highly intolerant. *J Clin Lipidol*. 2017;11:24-33. Available at: <https://www.acc.org/latest-incardiology/ten-points-to-remember/2017/05/03/10/43/statin-associated-muscle-symptoms>. Accessed December 5, 2019.
11. Thompson PD, Panza G, Zaleski A, et al. Statin-associated side effects. *JACC* 2016;67(20):2395- 2410.
12. American Diabetes Association. 10. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes-2019. *Diabetes Care*. 2019 Jan;42(Suppl 1):S103-S123.
13. Goff DC Jr, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014 Jun 24;129(25 Suppl 2):S49-73.

Nonformulary	
Brand Name	GenericName
VIGAMOX OPTHALMIC SOLUTION	moxifloxacin

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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 04/2019.
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 04/2019.

Nonformulary	
Brand Name	Generic Name
VIIBRYD	vilazodone

CRITERIA FOR COVERAGE/NONCOVERAGE

VIIBRYD is indicated for the treatment of major depressive disorder (MDD). It is a selective serotonin reuptake inhibitor (SSRI) and 5-HT_{1A} 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, paroxetine, sertraline, venlafaxine (including extended-release), duloxetine (20, 30, and 60 mg), 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:

1. Viibryd prescribing information. Irvine, CA. Allergan. Rev 1/2017.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: www.micromedexsolutions.com.libproxy.uthscsa.edu. Accessed 9/9/17.
3. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer.
4. Gelenberg AJ, Freeman MP. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. American Psychiatric Association. 2010.
5. Rickels K, Athanasiou M, et al. Evidence for efficacy and tolerability of vilazodone in the treatment of major depressive disorder: a randomized, double-blind, placebo-controlled trial. *J Clin Psychiatry*. 2009;70(3):326-333.
6. Khan A, Cutler AJ, et al. A randomized, double-blind, placebo-controlled, 8-week study of vilazodone, a serotonergic agent for the treatment of major depressive disorder. *J Clin Psychiatry*. 2011;72:441-447.
7. Croft HA, Pomara N, et al. Efficacy and safety of vilazodone in major depressive disorder: a randomized, double-blind, placebo-controlled trial. *J Clin Psychiatry*. 2014 Nov;75(11):e1291-1298.
8. Mathews M, Gommoll C, et al. Efficacy and safety of vilazodone 20 and 40 mg in major depressive disorder: a randomized, double-blind, placebo-controlled trial. *Int Clin Psychopharmacol*. 2015;30(2):67-74.

Brand Name	Generic Name
VIMPAT Oral Tablets, Oral Solution	Lacosamide Oral Tablets, Oral Solution

CRITERIA FOR COVERAGE/NONCOVERAGE

Lacosamide (tablets) a functionalized amino acid, is indicated as monotherapy or adjunctive therapy in patients 4 years and older for partial-onset seizures and is also indicated as adjunctive therapy in patients 4 years and older for primary generalized tonic-clonic seizures..

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

- 1.) The member is ≥ 4 years old.
- 2.) Diagnosis of partial-onset seizures or primary generalized tonic-clonic seizures
- 3.) The member has first tried and failed, or has a contraindication or intolerance to TWO different formulary anticonvulsants.

Dosage:

- i. Adults (17 years and older) initial adjunct therapy = 50mg BID.
- ii. Adults (17 years and older) initial monotherapy = 100mg BID.
- iii. Max dose = 400mg/day
- iv. Renal (severe)/Hepatic impairment (mild to moderate) = 300 mg/day.
- v. Children ≥ 4 to 17 years:
 - a. 11 to <30 kg: Oral: Initial monotherapy: 1 mg/kg/dose twice daily; may be increased at weekly intervals by 1 mg/kg/dose twice daily based on response and tolerability.
 - b. 30 to <50 kg: Oral: Initial: 1 mg/kg/dose twice daily; may be increased at weekly intervals by 1 mg/kg/dose twice daily based on response and tolerability.
 - c. ≥ 50 kg: Oral: Initial (monotherapy and adjunctive therapy): 50 mg twice daily; may be increased at weekly intervals of 50 mg twice daily based on response and tolerability.

Initial/Continuation approval length: 12 months

Continuation Criteria: Consistent/compliant fill history. Chart notes documenting a positive response to therapy noted as a reduction in seizure frequency and/or severity.

Exclusions: VIMPAT use is not recommended in patients with severe hepatic impairment.

Sources:

1. *VIMPAT medication guide Revised: 06/2019.*
2. *Micromedex*

Nonformulary – WEIGHT LOSS AGENTS	
Brand Name	Generic Name
Bontril	Phendimetrazine tablets, ER capsules
Contrave	Naltrexone/bupropion ER tablet
Didrex/Regimex	Benzphetamine tablet
Diethylpropion	Tablets, ER capsules
Fastin/Adipex-P/Suprenza	Phentermine capsules, tablets, disintegrating
Qsymia	Phentermine/topiramate capsule
Saxenda	Liraglutide injection
Wegovy	Semaglutide injection
Xenical/Alli	Orlistat (rx/otc)

CRITERIA FOR COVERAGE/NONCOVERAGE

*****Note: Belviq (lorcaserin): In February 2020, the US Food and Drug Administration (FDA) asked the manufacturer of lorcaserin to voluntarily withdraw lorcaserin from the US market because of clinical trial data showing an increased occurrence of cancer**

Weight loss agents will be approved for initial approval when following criteria are met:

- Member meets age requirements:
 - Contrave, Qsymia, Saxenda, Wegovy 18 years of age and older
 - Benzphetamine, Diethylpropion, Phendimetrazine, Phentermine: 17 years of age and older
 - Xenical: 12 years of age and older
 - OTC (over-the-counter) Alli: 18 years of age and older

AND

- Member has a BMI ≥ 30 kg/m² OR a BMI ≥ 27 kg/m² with at least one weight-related risk factors (for examples, diabetes, dyslipidemia, hypertension, coronary heart disease, sleep apnea).

AND

- Member has been on a weight loss regimen of a low calorie diet, increased physical activity, and behavioral modifications for at least 3-6 months AND failed to achieve weight loss.

AND

- Member will continue with behavioral modification and a reduced calorie diet.

Initial approval length: 4 months.

Weight loss agents will be approved for reauthorization when following criteria are met:

- Documented current weight showing a weight loss of at least 4% of baseline body weight or BMI

Re-authorization approval length: 12 months.

Contrave, Qsymia:

- Not recommended in patients with cardiovascular disease (hypertension or coronary heart disease).

Phentermine, benzphetamine, phendimetrazine, diethylpropion:

- Not recommended in patients with coronary heart disease, uncontrolled hypertension, hyperthyroidism, or in patients with a history of drug abuse. Phentermine abuse is low.

Xenical/OTC (over-the-counter) Alli:

- Not recommended in patients with cholestasis or malabsorption syndrome

Saxenda, Wegovy:

- Not indicated for the treatment of type 2 diabetes mellitus
- Saxenda should not be used in combination with any other Glucagon-Like Peptide-1 (GLP-1) Receptor agonists or insulin (Saxenda has not been studied in patients taking insulin).

Exclusions:

- Prevention of diabetes in individuals with BMI < 30 kg/m²
- Combination appetite suppressant therapy
- Treatment of hyperlipidemia in non-obese patients.
- Treatment of binge-eating disorder in non-obese patients.

References:

1. AHA/ACC/TOS Prevention Guideline: 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults: A Report to the American College of Cardiology/American Health Association Task Force on Practice Guidelines and The Obesity Society. *Circulation*. 2014; 129:S102-138. Available at: <https://www.ahajournals.org/doi/full/10.1161/01.cir.0000437739.71477.ee>. Accessed on February, 2020.
2. Garvey WT, Mechanick JL, Brett EM, et al; Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocrine Pract*. 2016; 22 (Suppl 3); 1-203. Available at: <https://journals.aace.com/doi/pdf/10.4158/EP161365.GL>. Accessed on February, 2020.
3. Perreault, L. Obesity in Adults: drug therapy. UpToDate, Waltham, MA. Accessed on February 29, 2020.
4. Contrave tablets [prescribing information]. La Jolla, CA: Orexigen Therapeutics; December 2018.
5. Qsymia capsules [prescribing information]. Mountain View, CA: Vivus, Inc.; December 2018.
6. Saxenda tablets [prescribing information]. Plainsboro, NJ: NovoNordisk; January 2020.
7. Xenical capsules [prescribing information]. Nutley, NJ: Roche Laboratories; December 2018.
7. Adipex-P tablets and capsules [prescribing information]. Horsham, PA: Teva Pharmaceuticals; January 2019.

NON FORMULARY	
Brand Name	Generic Name
XELJANZ XR	tofacitinib

CRITERIA FOR COVERAGE/NON-COVERAGE

*****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

- Prescribed by or in consultation with a rheumatologist.
- Age \geq 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or prescriber attestation.
- Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
 - Methotrexate
 - Hydroxychloroquine
 - Leflunomide
 - Sulfasalazine
- 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).
- 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:

1. Xeljanz prescribing information. New York, N.Y. Pfizer Inc. Rev May 2018.
2. Menter A, Gottlieb A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50.
3. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. *JAMA Dermatol* 2015; 151:87.
4. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010.
5. Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res*. 2016 Jan;68(1):1-25.

Brand Name	Generic Name
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, levofloxacin, norfloxacin, 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:

1. Vilstrup, H, Amodio, P, et al. AASLD Practice Guideline: Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver.
2. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 05/2019.
3. Facts& Comparisons Answers at <http://online.factsandcomparisons.com>. Accessed 05/2019.
4. Centers for Disease Control and Prevention. CDC Health Information for International Travel 2016. New York: Oxford University Press; 2016. Chapter 2, Table 2-06.

5. Ford AC, Moayyedi P, et al. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. *Am J Gastroenterol* 2014;109:S2-S26;doi:10.1038/ajg.2014.

NONFORMULARY	
Brand Name	Generic Name
XIIDRA	lifitegrast

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.
10. Documentation or prescription claim history supporting the trial and failure of a 30 day trial of Restasis

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:

1. Xiidra (lifitegrast ophthalmic solution 5%). Prescribing Information. Shire US Inc. Lexington, MA. 2016.
2. Jones L, Downie LE, Korb D, Benitez-Del-Castillo JM, Dana R, Deng SX, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf*. 2017 Jul. 15 (3):575-628.
3. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. American Academy of Ophthalmology; 2013. URL: www.aao.org/ppp.
4. Shtein, RM. Dry Eyes. UpToDate. Waltham, MA. Updated Jun 2018.

Non Formulary	
Brand Name	Generic Name
XYREM	sodium oxybate oral solution
XYWAV	oxybate salts oral solution
SUNOSI	solriamfetol
WAKIX	pitolisant

CRITERIA FOR COVERAGE/NON-COVERAGE

Xyrem/Xywav is a central nervous system depressant indicated for the treatment of cataplexy and excessive daytime sleepiness (EDS) in narcolepsy. It may only be dispensed to patients enrolled in the Xyrem/Xywav REMS Program.

Xyrem/Xywav is required to be taken at bedtime while in bed and again 2.5 to 4 hours later. The dose of Xyrem/Xywav should be titrated to effect. The efficacy and safety of Xyrem/Xywav at doses higher than 9 gm/night have not been investigated, and doses greater than 9 gm/night ordinarily should not be administered.

Wakix (pitolisant) is a wakefulness-promoting agent (selective histamine 3 (H₃) receptor antagonist/inverse agonist), indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

Sunosi (solriamfetol) is a wakefulness-promoting agent (dopamine and norepinephrine reuptake inhibitor), indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA)

XYREM/XYWAV/SUNOSI/WAKIX will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1. The member is 7 years of age (Xyrem or Xywav only) 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, dextmethylphenidate, 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: **Xyrem/Xywav:** Up to 540 ml per 30 days. **Wakix:** up to 35.6mg/day. **Sunosi:** up to 150mg/day.

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/Xywav/Wakix/Sunosi.

Xyrem/Xywav 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.

Sunosi Exclusions:

1. A member concomitantly using (or within 14 days) a monoamine oxidase inhibitor, verified by prescription claims history. This applies to new and continuation Sunosi requests.

Wakix Exclusions:

1. A member with confirmed hypersensitivity to Wakix or any component of the formulation; severe hepatic impairment. This applies to new and continuation Wakix requests

References:

1. Xyrem prescribing information. Indianapolis, IN. Jazz Pharmaceuticals, Inc. Rev Nov 2017.
2. Morgenthaler TI, Kapur VK, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin: An American Academy of Sleep Medicine Report.
3. Wise MS, Arand DL, et al. Treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine Review.
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)

Covered products	Brand or generic Name
zolpidem ER	AMBIEN CR

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.

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:

3. 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 (Non-Formulary, 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 (Non-Formulary) 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.

Medication	Recommended Dosing per Night	
	Men	Women
zolpidem ER	6.25 – 12.5 mg	6.25 mg
zolpidem sublingual	3.5 mg	1.75 mg
Edluar	5-10 mg	5 mg
Zolpimist	5-10 mg	5 mg

Exclusions:

1. Use concurrently with other sedative hypnotics or medications used to treat insomnia including Xyrem (sodium oxybate) or alternate formulations of Zolpidem.

References:

1. Sateia M, Buysse D, et al. Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med.* 2017;12(2):307-349.
2. Zolpimist full prescribing information. ECR Pharmaceuticals. Richmond, Virginia.
3. Edluar full prescribing information. Somerset, NJ. Meda Pharmaceuticals Inc.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com.libproxy.uthscsa.edu>. Accessed 04/2019.
5. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: <http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/>. Accessed 04/2019.

Brand Name	Generic Name
ZORTRESS	Everolimus

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

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

Covered Products	GenericName
ZYVOX oral suspension	Linezolid
Linezolid oral tablet	

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-susceptable 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.

References

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
2. Facts & Comparisons eAnswers at <http://online.factsandcomparisons.com>. Accessed 11/2016

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