



**Keystone 65 Rx HMO**  
**Personal Choice 65<sup>SM</sup> Rx PPO**  
**Select Option<sup>®</sup> Rx PDP**  
**2020 Utilization Management**  
**Criteria: Prior Authorization**

**PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION  
ABOUT SOME OF THE DRUGS WE COVER IN THIS PLAN**

This document was updated on 12/01/2020. For more recent information or other questions, please contact our Member Help Team: Keystone 65 at 1-844-352-1699, Personal Choice 65 at 1-888-879-4293, Select Option at 1-888-678-7009 or, for TTY/TDD users, 711, seven days a week from 8 a.m. to 8 p.m. Please note that on weekends and holidays from April 1 through September 30, your call may be sent to voicemail. Or, visit [www.ibxmedicare.com](http://www.ibxmedicare.com) to use our *Formulary (List of Covered Drugs)* search tool or view a downloadable document.

When this document refers to “we,” “us,” or “our,” it means Independence Blue Cross. When it refers to “plan” or “our plan,” it means Keystone 65 Rx, Personal Choice 65 Rx, and Select Option Rx.

You must generally use network pharmacies to use your prescription drug benefit. Benefits, formulary, pharmacy network, and/or copayments/coinsurance may change on January 1, 2021, and from time to time during the year.

Independence Blue Cross offers Medicare Advantage plans with a Medicare contract. Enrollment in Independence Medicare Advantage plans depends on contract renewal.

Keystone 65: Benefits underwritten by Keystone Health Plan East, a subsidiary of Independence Blue Cross — independent licensees of the Blue Cross and Blue Shield Association.

Personal Choice 65 & Select Option: Benefits underwritten by QCC Insurance Company, a subsidiary of Independence Blue Cross — independent licensees of the Blue Cross and Blue Shield Association.

## There may be restrictions to your drug coverage

Some covered drugs may have additional requirements or limits on coverage. We call this “utilization management.” These requirements and limits may include:

- **Prior Authorization (PA):** Our plan requires you or your physician to get prior authorization for certain drugs. This means that you will need to get approval from our plan before you fill your prescriptions. If you don’t get approval, our plan may not cover the drug. Drugs that require Prior Authorization are listed in this document.
- **Step Therapy (ST):** In some cases, our plan requires you to first try certain drugs to treat your medical condition before we will cover another drug for that condition. Drugs that require Step Therapy are listed in *2020 Utilization Management Criteria: Step Therapy*.
- **Quantity Limits (QL):** For certain drugs, our plan limits the amount of the drug that our plan will cover. Drugs that have Quantity Limits are listed in the *Keystone 65 Rx, Personal Choice 65 Rx, and Select Option Rx Formulary (List of Covered Drugs)*.

You can find out if your drug has any additional requirements or limits by looking in your plan *Formulary (List of Covered Drugs)*. You can also get more information about the restrictions applied to specific covered drugs by visiting [www.ibxmedicare.com](http://www.ibxmedicare.com).

You can ask our plan to make an exception to these restrictions or limits, or for a list of other similar drugs that may treat your health condition. Your *Formulary (List of Covered Drugs)* and *Evidence of Coverage* will have more information about the exception request process.

## How to use this document

This document, along with *2020 Utilization Management Criteria: Step Therapy*, is intended to be used with your *Formulary (List of Covered Drugs)*. If your prescription drug has the note “PA” in the “Requirements” column of the *Keystone 65 Rx, Personal Choice 65 Rx, and Select Option Rx Formulary (List of Covered Drugs)*, you can find more information on the restriction(s) in this document.

Locate your drug in the index on page 161. The restriction information includes:

- **Prior Authorization**
  - Covered uses
  - Exclusion criteria
  - Required medical information
  - Age restrictions
  - Prescriber restrictions
  - Coverage duration
  - Other criteria

Be sure to read all the information listed for your affected drug. If you have any questions, or need assistance with the information contained in this document, please call our Member Help Team: Keystone 65 at 1-844-352-1699, Personal Choice 65 at 1-888-879-4293, Select Option at 1-888-678-7009.

# ABILIFY MYCITE

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## Products Affected

- ABILIFY MYCITE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Deny if less than 18 years of age  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Indefinite   |
| Other Criteria               | Both of the following (1) inadequate response or inability to tolerate generic aripiprazole and (2) attestation that tracking ingestion of the medication is medically necessary |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# ABUSE DETERRENT OPIOID

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## Products Affected

- *hydrocodone bitartrate er oral capsule extended release 12 hour*
- XTAMPZA ER

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Remainder of contract year  |
| Other Criteria               | Documentation of one of the following: (1) Prior use of TWO generic opioids OR (2) BOTH of the following: (a) there is a history of or a potential for drug abuse among the individual or a member of the individual's household AND (b) documentation of current patient-prescriber opioid treatment agreement |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# ACTEMRA SQ

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists.   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to start of therapy.   |
| <b>Age Restrictions</b>             | Deny if age is less than 2 years for Polyarticular and Systemic juvenile rheumatoid arthritis. Deny if less than 18 years for all other Indications.  |
| <b>Prescriber Restrictions</b>      | Prescribed by a Rheumatologist  |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | ONE of the following: (1) For Polyarticular Juvenile rheumatoid arthritis: inadequate response or inability to tolerate BOTH adalimumab (Humira) and etanercept (Enbrel) OR documentation demonstrating that a trial may be inappropriate, (2) Systemic onset Juvenile chronic arthritis, (3) For moderate to severe rheumatoid arthritis: Inadequate response or inability to tolerate to TWO of the following: (a) Humira, (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR OR documentation demonstrating that a trial may be inappropriate, (4) For Giant Cell Arteritis: documentation of inadequate response/inability to tolerate oral corticosteroids |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# ACTHAR HP

## Products Affected

- ACTHAR

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, sensitivity to proteins or porcine origin, or where congenital infections are suspected in infants. OR Administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of H.P. Acthar Gel. Concurrent primary adrenocortical insufficiency or adrenocortical hyperfunction.  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | For diagnosis of IS: 2 years of age and younger, for diagnosis of MS: 18 years of age and older, for all other indications: 2 years of age and older   |
| <b>Prescriber Restrictions</b>      | Infantile spasms: pediatric neurologist or neonatologist, all other indications: neurologist, rheumatologist, nephrologist, pulmonologist, ophthalmologist, dermatologist, allergist, immunologist.  |
| <b>Coverage Duration</b>            | Infantile Spasms=1 yr. All Other=1 month   |
| <b>Other Criteria</b>               | Subject to Part B vs Part D review. Part D is medically necessary when ONE of the following is present: infantile spasms OR there has been inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone) and ONE of the following (1) acute exacerbation of multiple sclerosis currently receiving maintenance treatment for MS (e.g. Avonex, Betaseron, Copaxone, Tecfidera, etc.) (2) acute exacerbation of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis or ankylosing spondylitis currently receiving DMARD (3) nephrotic syndrome and ALL of the following (a) proteinuria greater than 3.5g/ 24 hours AND (b) serum albumin less than 3 mg/dL AND (c) peripheral edema (4) systemic lupus erythematosus, systemic dermatomyositis, severe erythema multiforme, Stevens-Johnson syndrome, serum sickness, inflammatory ophthalmic disease, or symptomatic sarcoidosis |

| PA Criteria           | Criteria Details                    |
|-----------------------|-------------------------------------|
| <b>Indications</b>    | All Medically-accepted Indications. |
| <b>Off Label Uses</b> |                                     |

# ACUTE HAE AGENTS

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## Products Affected

- BERINERT
- FIRAZYR
- *icatibant acetate*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescribed by an allergist or immunologist   |
| Coverage Duration            | Lifetime   |
| Other Criteria               | Subject to Part B vs Part D review. Part D is medically necessary when the following inclusion criterion is met: documentation of treatment of acute abdominal, facial or laryngeal attacks of hereditary angioedema (HAE) |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# ACUTE SEIZURE ACTIVITY AGENTS

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## Products Affected

- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE
- VALTOCO 20 MG DOSE
- VALTOCO 5 MG DOSE

| PA Criteria                  | Criteria Details                                |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Prescriber is a neurologist/epilepsy specialist |
| Coverage Duration            | Indefinite                                      |
| Other Criteria               |   |
| Indications                  | All Medically-accepted Indications.             |
| Off Label Uses               |   |

# ADEMPAS

## Products Affected

- ADEMPAS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent use of phosphodiesterase inhibitors, nitrates or nitric oxide donors, pregnancy   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if age is less than 18 years  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 6 month for initial authorization and 12 months for renewal authorizations   |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (1) Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II - IV AND (a) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography (b) Mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion, OR (2) Diagnosis of persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH. Re-authorization: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# ALLERGEN SPECIFIC IMMUNOTHERAPY (SL)

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## Products Affected

- GRASTEK

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Deny with documentation of any of the following: (1) Severe, unstable or uncontrolled asthma (2) History of eosinophilic esophagitis   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescriber is an allergist or immunologist.  |
| <b>Coverage Duration</b>            | Remainder of contract year   |
| <b>Other Criteria</b>               | Patient has a positive skin test or in vitro test for the listed pollen-specific IgE antibody AND Inadequate response or inability to tolerate intranasal corticosteroid and an antihistamine. Re-authorization criteria: Patient has experienced improvement in the symptoms of their allergic rhinitis or a decrease in the number of medications needed to control allergy symptoms |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# AMPYRA

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## Products Affected

- AMPYRA
- *dalfampridine er*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Deny if patient has history of seizure or moderate to severe renal impairment (CrCL less than or equal to 50 mL/min) |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Remainder of contract year   |
| <b>Other Criteria</b>               | Diagnosis of multiple sclerosis. REAUTHORIZATION CRITERIA: documentation of improvement in walking speed             |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# ANADROL

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## Products Affected

- ANADROL-50

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Remainder of contract year   |
| Other Criteria               | Documentation of ONE of the following: (1) Acquired aplastic anemia (2) Anemia of chronic renal failure (3) Antineoplastic adverse reaction - Myelosuppression (4) Fanconi's anemia (5) Pure red cell aplasia OR (6) Cachexia associated with AIDS |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# ARIKAYCE

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## Products Affected

- ARIKAYCE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | Deny if less than 18 years of age   |
| Prescriber Restrictions      | Deny if not prescribed by a pulmonologist or an infectious disease specialist |
| Coverage Duration            | Indefinite  |
| Other Criteria               |   |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# ARMODAFINIL/MODAFINIL

## Products Affected

- *armodafinil*
- *modafinil*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | For Narcolepsy, shift work sleep disorder or obstructive sleep apnea: prescribed by a neurologist or sleep specialist.  |
| <b>Coverage Duration</b>            | Narcolepsy, shift work sleep disorder or obstructive sleep apnea: Indefinite  |
| <b>Other Criteria</b>               | FOR NARCOLEPSY: Documentation of a diagnosis of Narcolepsy. FOR OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS): diagnosis confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and documentation that the medication is being used as an adjunct treatment for the underlying obstruction. FOR SHIFT WORK SLEEP DISORDER (SWSD): 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (i.e., disturbed chronobiologic rhythmicity), AND 3) Documentation that the member has no medical or mental disorder accounting for the symptoms |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# BENLYSTA SC

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## Products Affected

- BENLYSTA SUBCUTANEOUS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Subject to Part B vs Part D review. Part D is medically necessary when BOTH of the following are met: (1) documentation of active, autoantibody-positive, systemic lupus erythematosus (SLE) AND (2) patient is receiving concurrent treatment with at least ONE of the following: steroids, antimalarials, immunosuppressants, nonsteroidal anti-inflammatory drugs (NSAIDS) |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# BRAND ORAL FENTANYL

## Products Affected

- *fentanyl citrate buccal* MCG, 400 MCG, 600 MCG, 800 MCG
- FENTORA BUCCAL TABLET 100 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- SUBSYS SUBLINGUAL LIQUID 100 MCG, 200

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.   |
| <b>Coverage Duration</b>            | Remainder of contract year   |
| <b>Other Criteria</b>               | Documentation of ALL of the following: (1) pain associated with cancer, (2) long-acting pain medication regimen, (3) member is opioid tolerant as demonstrated by adherence for one week or more of any of the following regimens: at least 25mcg of transdermal fentanyl hourly, 30mg of oxycodone daily, 60mg of oral morphine daily, 8mg of oral hydromorphone daily, 25mg of oral oxymorphone daily or an equianalgesic dose of another opioid AND (4) inadequate response to a generic oral transmucosal fentanyl citrate product |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# CARBAGLU

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## Products Affected

- CARBAGLU

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Indefinite   |
| Other Criteria               | Hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# CAYSTON

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## Products Affected

- CAYSTON

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Deny if less than 7 years  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Remainder of contract year   |
| Other Criteria               | Documentation of all of the following: (1) cystic fibrosis, (2) Pseudomonas Aeruginosa in the lungs, (3) Susceptibility results indicating that the Pseudomonas aeruginosa is sensitive to aztreonam AND (4) FEV1 between 25% and 75% of predicted |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# CERDELGA

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## Products Affected

- CERDELGA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Patient is CYP2D6 Ultra Rapid Metabolizer (URM), concurrent use of Class 1A or Class III anti-arrhythmic, long QT syndrome, patient has pre-existing cardiac disease   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if less than 18 years   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Diagnosis of Type 1 Gaucher disease and patient is CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-cleared test for determining CYP2D6 genotype |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# CGRP ANTAGONISTS

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## Products Affected

- AIMOVIG
- AJOVY
- EMGALITY

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Deny if less than 18 years of age  |
| Prescriber Restrictions      | Prescribed by or in consultation with a neurologist or headache specialist certified by the United Council for Neurologic Subspecialties, or pain specialist |
| Coverage Duration            | 6 months for initial authorization, 12 months for reauthorization  |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>For Migraines (Initial): Approved when ONE of the following inclusion criteria are met: (1) Diagnosis of episodic migraines defined as 4 to 14 headache days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (a) topiramate (b) divalproex sodium/ valproic acid (c) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (d) tricyclic antidepressants: amitriptyline, nortriptyline (e)SNRI antidepressants: venlafaxine, duloxetine OR (2) Diagnosis of chronic migraines defined as greater than or equal to 15 headache days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (i) topiramate (ii) divalproex sodium/ valproic acid (iii) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (iv) tricyclic antidepressants: amitriptyline, nortriptyline (v)SNRI antidepressants: venlafaxine, duloxetine (REAUTHORIZATION criteria): BOTH of the following: (1) Prescribed by or in consultation with a neurologist or headache specialist (2) Documentation of response to therapy as defined by a reduction in headache days per month (defined as at least 4 hours duration and moderate intensity) For Episodic Cluster Headaches (Initial): Diagnosis of episodic cluster headaches (Applies only to Emgality). Diagnosis of episodic cluster headache and ALL of the following: (a) Member has experienced at least 2 cluster periods lasting 6 days to 365 days, separated by pain-free periods lasting at least three months, (b) Emgality 100mg/ml will not be used in combination with another CGRP inhibitor. (REAUTHORIZATION CRITERIA): BOTH of the following: (1) Prescribed by or in consultation with a neurologist or headache specialist (2) Documentation of response to therapy as defined by a reduction in weekly cluster headache attacks</p> |
| <b>Indications</b>    | All Medically-accepted Indications.  |
| <b>Off Label Uses</b> |  |

# CHOLBAM

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## Products Affected

- CHOLBAM

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Deny if there is documentation of extrahepatic manifestations of bile acid synthesis disorders due to single enzyme defects or peroxisomal disorders including Zellweger spectrum disorders  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Initial criteria: 3 months. Re-authorization criteria: indefinite  |
| <b>Other Criteria</b>               | Documentation of One of the following: (a) Treatment of bile acid synthesis disorder due to single enzyme defect (b) Adjunctive treatment of peroxisomal disorder including Zellweger spectrum disorder in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption. Re-authorization criteria: Documentation of improved liver function tests from the start of treatment. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# CIALIS

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## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | Concurrent use of nitrates.   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Diagnosis of BPH and an inadequate response or inability to tolerate an alpha blocker (e.g. tamsulosin, terazosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride). |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# CIMZIA

## Products Affected

- CIMZIA PREFILLED
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to start of therapy.  |
| <b>Age Restrictions</b>             | Deny if less than 18 years   |
| <b>Prescriber Restrictions</b>      | CD: Prescribed by or in consultation with a gastroenterologist. RA, AS, nr-axSpA: Prescribed by or in consultation with a rheumatologist. PsA: prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis: Prescribed by or in consultation with a dermatologist.   |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (1) for diagnosis of Ankylosing Spondylitis: inadequate response or inability to tolerate both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate, (2) for Psoriatic Arthritis: inadequate response or inability to tolerate TWO of the following: Humira, Xeljanz/Xeljanz XR, Enbrel or documentation demonstrating that a trial may be inappropriate, (3) for Plaque Psoriasis: inadequate response or inability to tolerate to BOTH of the following: (a) ONE of the following: (i) Humira, (ii) Enbrel, or (iii) Skyrizi AND (b) Cosentyx OR documentation demonstrating that a trial may be inappropriate, (4) for Rheumatoid Arthritis: inadequate response or inability to tolerate to TWO of the following: (a) Humira, (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR OR documentation demonstrating that a trial may be inappropriate, (5) for diagnosis of Crohn's Disease: inadequate response or inability to tolerate adalimumab (Humira) or documentation demonstrating that a trial may be inappropriate, (6) Diagnosis of Non-radiographic axial Spondyloarthritis AND inadequate response or inability to tolerate two NSAIDs OR Cosentyx OR documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |

| PA Criteria    | Criteria Details |
|----------------|------------------|
| Off Label Uses |                  |

# CINRYZE

## Products Affected

- CINRYZE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | Deny if less than 6 years of age  |
| Prescriber Restrictions      | Prescribed by an allergist or immunologist  |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Subject to Part B vs Part D review. Part D is medically necessary when ALL of the following criteria are met: (1) Diagnosis of hereditary angioedema (HAE) (2) history of laryngeal edema or airway compromise with an episode of HAE or a history of at least 2 HAE attacks per month, AND (3) inadequate response or inability to tolerate 17 alpha-alkylated androgens (e.g. danazol, oxandrolone, stanozolol) or anti-fibrinolytic agents (e.g. epsilon aminocaproic acid, tranexamic acid) for HAE prophylaxis |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# CORLANOR

## Products Affected

- CORLANOR

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Chronic Heart Failure: (1)Diagnosis of chronic heart failure. (2) stable, symptomatic chronic heart failure (3) left ventricular ejection fraction less than or equal to 35% and (4) sinus rhythm with resting heart rate greater than or equal to 70 beats per minute. Chronic Heart Failure due to Dilated Cardiomyopathy in pediatric patients ages 6 months and older: (1) Diagnosis of chronic heart failure due to dilated cardiomyopathy (2) Patient is in sinus rhythm. |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by a cardiologist  |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Patient is clinically stable for at least 4 weeks on an optimized regimen which includes: (a) maximally tolerated doses of beta blockers or inability to tolerate beta blockers, (b) ACE inhibitors or ARBs or inability to tolerate ACE inhibitor or ARB   |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# COSENTYX

## Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to start of therapy.   |
| <b>Age Restrictions</b>             | Deny if less than 18 years  |
| <b>Prescriber Restrictions</b>      | Plaque psoriasis : Prescribed by a dermatologist. PsA: Prescribed by a rheumatologist or dermatologist. AS, nr-axSpA: Prescribed by a rheumatologist.   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | ONE of the following: (1) For diagnosis of plaque psoriasis: Inadequate response or inability to tolerate to ONE of the following: (a) Humira, (b) Enbrel, (c) Skyrizi OR documentation demonstrating that a trial may be inappropriate, (2) for psoriatic arthritis: inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate, (3) ankylosing spondylitis: inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate, or (4) for non-radiographic axial spondyloarthritis (nr-axSpA): inadequate response or inability to tolerate two NSAIDs |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# CRESEMBA [ORAL]

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## Products Affected

- CRESEMBA ORAL

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Deny if less than 18 years   |
| Prescriber Restrictions      | Prescribed by or in consultation with an infectious disease specialist   |
| Coverage Duration            | Remainder of contract year   |
| Other Criteria               | Documentation of either of the following: (1) for use in the treatment of invasive aspergillosis after inadequate response or inability to tolerate oral Voriconazole (oral Vfend) OR (2) for a diagnosis of mucormycosis. |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# CYSTARAN

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## Products Affected

- CYSTARAN

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Remainder of contract year   |
| Other Criteria               | Documentation of BOTH of the following: (1) diagnosis of cystinosis AND (2) patient has corneal cystine crystal accumulation |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# DAYVIGO

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## Products Affected

- DAYVIGO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Insomnia: (1) Diagnosis of insomnia. (2) Inadequate response or inability to tolerate generic ramelteon (Rozerem). |
| Age Restrictions             | (Insomnia): Apply if member is greater than or equal to 65 years   |
| Prescriber Restrictions      |  |
| Coverage Duration            | (Insomnia): Remainder of contract year   |
| Other Criteria               |  |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# DEFERASIROX

## Products Affected

- *deferasirox*
- *deferasirox granules*
- JADENU
- JADENU SPRINKLE

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | CrCl less than 40 mL/min or serum creatinine more than 2 times the age-appropriate ULN, platelet counts less than 50,000/mL  |
| <b>Required Medical Information</b> | Serum ferritin levels consistently greater than 300 mcg/L (as demonstrated with at least two lab values within the previous two months)  |
| <b>Age Restrictions</b>             | Iron Overload Due to Blood Transfusions: 2 years of age or older. NTD: 10 years of age or older  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Initial approval=3 months, Reauthorization=6 months  |
| <b>Other Criteria</b>               | Documentation of ONE of the following diagnoses: (1) Chronic iron overload in nontransfusion-dependent thalassemia syndromes and all of the following: (a) patient 10 years and older (b) liver iron concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) and (c) serum ferritin greater than 300 mcg/L OR (2) For the treatment of chronic iron overload caused by blood transfusions (transfusional hemosiderosis) in patients 2 years and older<br>Reauthorization criteria: One of the following: (1) Documentation of a decreased serum ferritin level compared with the baseline level for transfusion- dependent anemia or (2) Documentation of a decreased serum ferritin level compared with the baseline level or reduction in LIC (liver iron concentration) for Non-transfusion dependent thalassemia syndrome |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# DOPTELET

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## Products Affected

- DOPTELET ORAL TABLET 20 MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Documentation of baseline platelet count less than 50,000/mcL                        |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | For Chronic Liver Disease = 1 month. For Chronic Immune Thrombocytopenia = 12 months |
| Other Criteria               |  |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# DUPIXENT

## Products Affected

- DUPIXENT

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | (Atopic Dermatitis): Member is 6 years of age or older. (Asthma): Member is 12 years of age or older. (Chronic Rhinosinusitis with Nasal Polyposis): Member is 18 years of age or older   |
| <b>Prescriber Restrictions</b>      | For atopic dermatitis: prescriber is a dermatologist, allergist, immunologist for asthma: prescriber is an allergist, immunologist or pulmonologist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (A) Diagnosis of atopic dermatitis BOTH of the following: (1) diagnosis of moderate-severe atopic dermatitis AND (2) inadequate response or inability to tolerate BOTH of the following (a) one topical steroid (medium potency or higher) AND (b) topical tacrolimus. (B) Diagnosis of asthma documentation is provided of both of the following: (1) ONE of the following: (a) Member has oral corticosteroid-dependent asthma or (b) Member has blood eosinophil levels of at least 150 cells/mcL at baseline or at least 300 cells/mcL within the past 12 months AND (2) the requested medication will be used in addition to BOTH of the following: (a) medium to high dose inhaled corticosteroid (e.g. greater than or equal to 500mcg fluticasone propionate equivalent/day) AND (b) one additional controller medication. (C) Diagnosis of chronic rhinosinusitis with nasal polyposis and concurrent use of intranasal corticosteroid. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# EMFLAZA

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## Products Affected

- EMFLAZA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | Patient is 2 years of age or older                                      |
| Prescriber Restrictions      | Prescribed by a neurologist   |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Inadequate response or inability to tolerate prednisone or prednisolone |
| Indications                  | All Medically-accepted Indications.                                     |
| Off Label Uses               |   |

# EMGALITY-CLUSTER HEADACHES

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## Products Affected

- EMGALITY (300 MG DOSE)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | Deny if less than 18 years of age   |
| Prescriber Restrictions      | Prescribed by or in consultation with a neurologist or headache specialist certified by the United Council for Neurologic Subspecialties, pain specialist |
| Coverage Duration            | 3 months for initial, 12 months for reauthorization   |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>For Migraines (Initial): Approved when ONE of the following inclusion criteria are met: (1) Diagnosis of episodic migraines defined as 4 to 14 headache days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (a) topiramate (b) divalproex sodium/ valproic acid (c) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (d) tricyclic antidepressants: amitriptyline, nortriptyline (e)SNRI antidepressants: venlafaxine, duloxetine OR (2) Diagnosis of chronic migraines defined as greater than or equal to 15 headache days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (i) topiramate (ii) divalproex sodium/ valproic acid (iii) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (iv) tricyclic antidepressants: amitriptyline, nortriptyline (v)SNRI antidepressants: venlafaxine, duloxetine (REAUTHORIZATION criteria): BOTH of the following: (1) Prescribed by or in consultation with a neurologist or headache specialist (2) Documentation of response to therapy as defined by a reduction in headache days per month (defined as at least 4 hours duration and moderate intensity) For Episodic Cluster Headaches (Initial): Diagnosis of episodic cluster headache and ALL of the following: (a) Member has experienced at least 2 cluster periods lasting 6 days to 365 days, separated by pain-free periods lasting at least three months, (b) Emgality will not be used in combination with another CGRP inhibitor. (REAUTHORIZATION CRITERIA): BOTH of the following: (1) Prescribed by or in consultation with a neurologist or headache specialist (2) Documentation of response to therapy as defined by a reduction in weekly cluster headache attacks.</p> |
| <b>Indications</b>    | All Medically-accepted Indications.  |
| <b>Off Label Uses</b> |  |

# EMSAM

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## Products Affected

- EMSAM

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Documentation that at least 14 days has elapsed after discontinuation of antidepressants without long half-lives OR documentation at least 5 weeks has elapsed after discontinuation with antidepressants with long half-lives e.g. Fluoxetine. |
| <b>Age Restrictions</b>             | Deny in patients less than 18 years of age.   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Documentation of diagnosis of major depressive disorder AND a documented inadequate response or inability to tolerate ONE SSRI or SNRI  |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# ENBREL

## Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to start of therapy.   |
| <b>Age Restrictions</b>             | Deny if patient is less than 2 years  |
| <b>Prescriber Restrictions</b>      | RA, PJIA, AS: Prescribed by a rheumatologist. PsA: Prescribed by a rheumatologist or dermatologist. Plaque Psoriasis: Prescribed by a dermatologist.  |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Documentation of a previous trial with infliximab (Remicade) OR ONE of the following: (1) For moderate to severe Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA) or Juvenile Idiopathic Arthritis (PJIA): Inadequate response or inability to tolerate ONE of the following: methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine OR (2) For moderate to severe Plaque Psoriasis: inadequate response or inability to tolerate ONE of the following drugs: Topical Calcipotriene, Topical Anthralin, Topical Steroids, Topical immunomodulators (Elidel, Protopic), Topical retinoids OR (3) For Ankylosing Spondylitis (AS): Inadequate response or inability to tolerate two NSAIDs. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# ENDARI

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## Products Affected

- ENDARI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Prescribed by a hematologist or oncologist  |
| Coverage Duration            | Indefinite  |
| Other Criteria               | One of the following: (a) Member is using Endari with concurrent hydroxyurea therapy, OR (b) Member has an inadequate response or inability to tolerate hydroxyurea AND Member has had 2 or more painful sickle cell crises within the past 12 months |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# EPIDIOLEX

## Products Affected

- EPIDIOLEX

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | baseline CBC, serum transaminases and total bilirubin prior to initiating therapy   |
| <b>Age Restrictions</b>             | Deny if less than 1 years of age  |
| <b>Prescriber Restrictions</b>      | Dravet, Lennox Gaustaut, or Tuberous Sclerosis Complex: Prescribed by a neurologist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | <p>Dravet Syndrome: Approved when BOTH of the following inclusion criteria are met: (1) Documentation of an inadequate response or inability to tolerate ONE of the following: (a) clobazam (b) valproic acid (c) levetiracetam (d) topiramate and (2) Documentation of concurrent use with additional anti-epileptic(s)</p> <p>Lennox-Gastaut Syndrome: Approved when BOTH of the following inclusion criteria is met: (1) Documentation of an inadequate response or inability to tolerate ONE of the following (a) valproic acid (b) lamotrigine (c) topiramate (d) felbamate (e) rufinamide (f) clobazam and (2) Documentation of concurrent use with additional anti-epileptic(s)</p> <p>Tuberous Sclerosis Complex (TSC): Approved when BOTH of the following: (1) Inadequate response or inability to tolerate ONE of the following: (a) clobazam (b) valproic acid (c) levetiracetam (d) topiramate and (2) Concurrent use with additional anti-epileptic(s).</p> |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# EUCRISA

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## Products Affected

- EUCRISA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | Patient is 2 years of age or older  |
| Prescriber Restrictions      |   |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Inadequate response or inability to tolerate at least ONE of the following: (a) topical tacrolimus OR topical pimecrolimus , OR (b) generic, prescription medium potency or higher topical steroid. |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# EVEKEO

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## Products Affected

- *amphetamine sulfate*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | For ADHD: Patient is 3 years of age or older For Narcolepsy: Patient is 6 years of age or older. |
| Prescriber Restrictions      |  |
| Coverage Duration            | Remainder of Contract Year   |
| Other Criteria               |  |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# EVENITY

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## Products Affected

- EVENITY

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Osteoporosis defined as T score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR history of osteoporotic fracture (i.e. hip, spine, etc.)   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Member has had an inadequate response or inability to tolerate BOTH of the following: (a) at least one of the following (i) bisphosphonates, (ii) hormone replacement therapy, (iii) selective-estrogen receptor modulators (SERMs), AND (b) Denosumab (Prolia). Documentation that cumulative lifetime therapy does not exceed 12 months. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# FASENRA

## Products Affected

- FASENRA
- FASENRA PEN

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Patient is 12 years of age or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with pulmonologist or allergy/immunology specialist   |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ALL of the following: 1) Diagnosis of severe asthma with eosinophilic phenotype as defined by ONE of the following at initiation of therapy (a) blood eosinophil levels are at least 150 cells/microliter if dependent on daily oral corticosteroids for at least 6 continuous months or (b) blood eosinophil levels are at least 300 cells/microliter AND 2) ONE of the following: a) Patient has had at least one asthma exacerbation requiring systemic corticosteroids within the past 12 months, or b) Any prior intubation for asthma exacerbation, or c) prior asthma-related hospitalization within the past 12 months, AND 3) Patient is currently treated with ONE of the following unless there is a contraindication or intolerance to these medications: a) high-dose inhaled corticosteroids (ICS) (e.g., greater than or equal to 500 mcg fluticasone propionate equivalent/day) AND an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline) OR b) one maximally-dosed combination ICS/LABA product) |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# FENTANYL CITRATE LOZENGE

## Products Affected

- *fentanyl citrate buccal*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.  |
| <b>Coverage Duration</b>            | Remainder of contract year  |
| <b>Other Criteria</b>               | Documentation of all of the following: (1) pain associated with cancer, (2) long acting medication regimen AND (3) member is opioid tolerant as demonstrated by adherence to one of the following regimens for at least one week: at least 25mcg of transdermal fentanyl hourly, 30mg of oxycodone daily, 60mg of oral morphine daily, 8mg of oral hydromorphone daily, 25mg of oral oxymorphone daily or an equianalgesic dose of another opioid |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# FERRIPROX

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## Products Affected

- *deferiprone*
- FERRIPROX

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Deny if less than 18 years   |
| Prescriber Restrictions      |  |
| Coverage Duration            | Remainder of contract year   |
| Other Criteria               | Documentation of both of the following inclusion criteria: transfusional iron overload due to thalassemia syndromes AND inadequate response or inability to tolerate current chelation therapy |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# FIRDAPSE

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## Products Affected

- FIRDAPSE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | history of seizures   |
| Required Medical Information |   |
| Age Restrictions             | Deny if less than 18 years of age   |
| Prescriber Restrictions      | Deny if not prescribed by or in consultation with a neurologist   |
| Coverage Duration            | 90 Days, indefinite for continuation  |
| Other Criteria               | Both of the following: (1) Neurological symptoms persist after treatment of malignancy, when malignancy is present and (2) Documentation the member has moderate to severe weakness that interferes with function.<br>CONTINUATION CRITERIA: Documentation is provided of a positive clinical response to therapy |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# GALAFOLD

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## Products Affected

- GALAFOLD

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Documentation that member has amenable galactosidase alpha gene (GLA) variant per FDA labeling information |
| Age Restrictions             | Deny if less than 16 years of age  |
| Prescriber Restrictions      | Prescribed by clinical genetics specialist   |
| Coverage Duration            | Initial: 6 months, reauthorization: indefinite   |
| Other Criteria               | REAUTHORIZATION: documentation of response to therapy  |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# GATTEX

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## Products Affected

- GATTEX

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 6 months   |
| Other Criteria               | Documentation of ALL of the following: (1) diagnosis of Short Bowel Syndrome AND (2) individual receives parenteral support at least three times per week for at least 12 months. REAUTH CRITERIA: Reduction in parenteral support from baseline (prior to initiation of Gattex therapy) |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# GROWTH HORMONES

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPRO SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 10 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 20 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 5 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED
- SAIZEN
- SAIZENPREP
- ZOMACTON

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | (1) Growth failure in children when all of the following inclusion criteria are met: (a) subnormal serum insulin-like growth factor-1 (IGF-1), (b) growth velocity less than or equal to 5 cm/year after 2 years of age, (c) documentation of bone age and (d) abnormal response from provocative testing, such as insulin-induced hypoglycemia test, levodopa, or clonidine. (2) Small for gestational age (SGA) with clinical documentation of no catch-up growth by 2 to 4 years of age. (3) Growth failure associated with chronic kidney disease (CKD), (4) Growth failure associated with Noonan Syndrome, Prader-Willi Syndrome, Turner Syndrome or short stature homeobox-containing gene (SHOX) deficiency, (5) Diagnostically confirmed Growth hormone deficiency in adults OR (6) Idiopathic short stature defined by height standard deviation score (SDS) less than or equal to 2.25 and documentation of growth velocity less than 25th percentile for bone age |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by an endocrinologist or nephrologist  |
| <b>Coverage Duration</b>            | 12 months   |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | CONTINUATION OF GROWTH HORMONE: for additional 12 months: Annual clinical re-evaluation by the treating endocrinologist, expected adult height not attained and documentation of expected adult height goal, AND one of the following criteria is met: (1) for Growth failure in children - normalization of IGF-1 (2) for Small for gestational age (SGA) - increase in growth velocity from baseline (3) for Growth failure associated with chronic kidney disease (CKD) - no history of renal transplant (4) for Growth failure associated with Noonan Syndrome, Prader-Willi, Turner Syndrome OR SHOX - documentation of clinical reevaluation by endocrinologist (5) for Growth hormone deficiency in adults - normalization of IGF-1: OR (6) Idiopathic short stature - increase in growth velocity from baseline |
| <b>Indications</b>    | All Medically-accepted Indications.   |
| <b>Off Label Uses</b> |   |

# HAEGARDA

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## Products Affected

- HAEGARDA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescribed by an allergist or immunologist   |
| Coverage Duration            | Indefinite   |
| Other Criteria               | ALL of the following criteria are met: (1) Diagnosis of hereditary angioedema (HAE) (2) history of laryngeal edema or airway compromise with an episode of HAE or a history of at least 2 HAE attacks per month, AND (3) inadequate response or inability to tolerate 17 alpha-alkylated androgens (e.g. danazol, oxandrolone, stanozolol) or anti-fibrinolytic agents (e.g. epsilon aminocaproic acid, tranexamic acid) for HAE prophylaxis |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# HETLIOZ

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## Products Affected

- HETLIOZ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Deny if not prescribed by a sleep specialist or neurologist   |
| Coverage Duration            | Remainder of contract year  |
| Other Criteria               | Diagnosis of a circadian period greater than 24 hours AND patient is totally blind (has no light perception). |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# HIGH DOSE OPIOIDS

## Products Affected

- *fentanyl transdermal patch 72 hour 100 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 62.5 mcg/hr, 75 mcg/hr, 87.5 mcg/hr*
- *hydromorphone hcl er oral tablet extended release 24 hour*
- *hydromorphone hcl oral tablet 4 mg, 8 mg*
- *methadone hcl oral solution*
- *methadone hcl oral tablet*
- *morphine sulfate er beads oral capsule extended release 24 hour 120 mg*
- *morphine sulfate er oral capsule extended release 24 hour 100 mg, 60 mg, 80 mg*
- *morphine sulfate er oral tablet extended release 100 mg, 200 mg, 60 mg*
- *oxycodone hcl er oral tablet er 12 hour abuse-deterrent 30 mg, 60 mg, 80 mg*
- *oxycodone hcl er oral tablet er 12 hour abuse-deterrent 40 mg*
- *oxycodone hcl oral tablet 30 mg*
- *oxymorphone hcl er oral tablet extended release 12 hour 20 mg, 30 mg*
- *oxymorphone hcl er oral tablet extended release 12 hour 40 mg*
- *oxymorphone hcl oral tablet 10 mg*
- *XTAMPZA ER*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Remainder of contract year   |
| <b>Other Criteria</b>               | NEW TO HIGH DOSE OPIOID THERAPY (morphine equivalent dose 90mg per day or greater): ONE of the following (A) pain associated with cancer OR (B) chronic non-cancer pain and BOTH of the following (1) member is opioid tolerant (e.g. at least one week where total daily dose is at least one of the following: 30mg of oxycodone, 60mg of oral morphine, 8mg of oral hydromorphone, 25mg of oral oxymorphone or an equianalgesic dose of another opioid) AND (2) the member has been evaluated for non-opioid prescription pharmacologic treatment prior to initiation of high dose opioid therapy. CONTINUING HIGH DOSE OPIOID THERAPY (morphine equivalent dose 90mg per day or greater): ONE of the following (1) pain associated with cancer OR (2) chronic non-cancer pain and ALL (a) member's pain has been assessed within the last 6 months AND (c) member has clinically meaningful improvement in pain and functioning that outweighs risks to patient safety AND (d) member is not being treated for substance abuse |

| PA Criteria           | Criteria Details                    |
|-----------------------|-------------------------------------|
| <b>Indications</b>    | All Medically-accepted Indications. |
| <b>Off Label Uses</b> |                                     |

# HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AGENTS

## Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Moderate-severe liver impairment, active liver disease, unexplained LFT abnormalities. Juxtapid: Pregnancy, concomitant use with strong or moderate CYP3A4 inhibitors.  |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by a cardiologist, endocrinologist, or lipid specialist.   |
| <b>Coverage Duration</b>            | 6 months  |
| <b>Other Criteria</b>               | Documentation of BOTH of the following: (1) diagnosis of Homozygous Familial Hypercholesterolemia with ONE of the following: (a) Genetic confirmation of 2 mutant alleles at the LDL receptor. Apo B, PCSK9, or ARH adaptor protein gene locus (b) Untreated LDL-C greater than 500 mg/dL or treated LDL cholesterol greater than or equal to 300 mg/dL or treated non-HDL cholesterol greater than or equal to 330 mg/dL together with either of the following: (i) Tendinous xanthoma prior to 10 years of age (ii) Elevated LDL cholesterol prior to lipid-lowering therapy consistent with HeFH in both parents AND (2) Inadequate response or inability to tolerate the combination of ONE high potency statin at the maximally tolerated dose (e.g., atorvastatin, rosuvastatin) with either ezetimibe or a Bile Acid Sequestrant (e.g. cholestyramine). REAUTHORIZATION CRITERIA: Documentation of reduction in LDL level since initiation of therapy with respective drug |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# HRM

## Products Affected

- *butalbital-acetaminophen oral capsule*
- *butalbital-acetaminophen oral tablet 50-300 mg, 50-325 mg*
- *butalbital-apap-caff-cod*
- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *butalbital-aspirin-caffeine oral capsule*
- *chlorzoxazone oral tablet 375 mg, 750 mg*
- *dipyridamole oral*
- *metaxalone*
- *methocarbamol oral*
- *promethazine hcl oral syrup*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- **PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG**

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Apply if patient is greater than or equal to 65 years  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Remainder of contract year   |
| <b>Other Criteria</b>               | Documentation that the risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# HRM ESTROGENS

## Products Affected

- AMABELZ
- BIJUVA
- CLIMARA PRO
- COMBIPATCH
- DIVIGEL TRANSDERMAL GEL 1 MG/GM
- DOTTI
- *estradiol oral*
- *estradiol transdermal*
- *estradiol-norethindrone acet*
- FYAVOLV
- JINTELI
- MENOSTAR
- MIMVEY
- *norethindrone-eth estradiol*
- PREFEST
- PREMARIN ORAL

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | Apply if patient is greater than or equal to 65 years   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Remainder of contract year  |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (1) Inadequate response or inability to tolerate vaginal estrogen preparations (e.g. vaginal tablets, rings, or cream, etc.) OR (2) Documentation that the risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# HRM KETOROLAC

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## Products Affected

- *ketorolac tromethamine oral*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Apply if patient is greater than or equal to 65 years  |
| Prescriber Restrictions      |  |
| Coverage Duration            | One Month  |
| Other Criteria               | Documentation of ONE of the following: (1) Inadequate response or inability to tolerate TWO alternative NSAIDs such as meloxicam, naproxen, celecoxib, ibuprofen, etc. OR (2) Documentation that the risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# HRM NON BENZODIAZEPINE HYPNOTICS

## Products Affected

- *eszopiclone oral tablet 3 mg*
- *zolpidem tartrate er oral tablet extended release 12.5 mg*
- *zolpidem tartrate oral tablet 10 mg*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | Apply if patient is greater than or equal to 65 years   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | 3 months for initial authorization, end of contract year for reauthorization  |
| <b>Other Criteria</b>               | Documentation that the risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly REAUTHORIZATION CRITERIA: documentation that prescriber is aware of the risk versus benefit of using the medication chronically (greater than 90 days) |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# HRM SHORT TERM SKELETAL MUSCLE RELAXANTS

## Products Affected

- *carisoprodol oral*
- *carisoprodol-aspirin-codeine*
- *cyclobenzaprine hcl er*
- *cyclobenzaprine hcl oral*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Apply if patient is greater than or equal to 65 years  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Acute muscle spasms= 3 weeks, all other indications= end of coverage year  |
| <b>Other Criteria</b>               | Documentation that the risk versus benefit has been assessed for this request of a high risk medication (HRM) in the elderly |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# HUMIRA

## Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PS/UV/ADOL HS START
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to start of therapy.  |
| <b>Age Restrictions</b>             | Deny if less than 2 years for JIA or Uveitis, less than 6 years for Crohn's disease, less than 12 years for hidradenitis suppurativa, less than 18 years for all other indications   |
| <b>Prescriber Restrictions</b>      | Prescribed by a Rheumatologist, Dermatologist, Ophthalmologist or Gastroenterologist accordingly   |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of a previous trial with infliximab (Remicade) OR ONE of the following: (1) For moderate to severe Rheumatoid Arthritis, Ankylosing Spondylitis, moderate to severe Juvenile Idiopathic Arthritis (JIA) , or Psoriatic Arthritis: inadequate response or inability to tolerate ONE of the following: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine, (2) For moderate to severe Plaque Psoriasis: inadequate response or inability to tolerate ONE of the following drugs: topical calcipotriene containing products, topical anthralin, topical steroids, topical immunomodulators (Elidel, Protopic), topical retinoids (3) For Crohn's Disease or Ulcerative Colitis: inadequate response or inability to tolerate ONE of the following: corticosteroid, Aminosalicylate, or Immunomodulators (ex. azathioprine or 6-mercaptopurine), (4) diagnosis of Hidradenitis suppurativa OR (5) diagnosis of non-infectious intermediate, posterior, or pan- uveitis and inadequate response or inability to tolerate BOTH of the following (1) ONE topical ophthalmic steroid AND (2) ONE oral corticosteroid |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# ILUMYA

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## Products Affected

- ILUMYA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of live vaccines prior to the start of therapy                                |
| <b>Age Restrictions</b>             | Deny if less than 18 years  |
| <b>Prescriber Restrictions</b>      | Prescribed by a dermatologist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Documentation of the following: plaque psoriasis and inadequate response or inability to tolerate both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# INBRIJA

## Products Affected

- INBRIJA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Prescribed by or in consultation with a neurologist   |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Documentation is provided of ALL of the following: (1) Member is receiving Inbrija in combination with carbidopa/levodopa containing product, (2) Member is experiencing intermittent OFF episodes, (3) member had inadequate response or inability to tolerate ONE of the following: (a) MAO-B inhibitor (e.g., rasagiline, selegiline), (b) Dopamine agonist (e.g., pramipexole, ropinirole), (c) COMT inhibitor (e.g., entacapone) |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# INCRELEX

## Products Affected

- INCRELEX

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Known or suspected malignancy, closed epiphyses, concurrent GH therapy  |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | Deny if less than 2 years   |
| <b>Prescriber Restrictions</b>      | Prescribed by a pediatric endocrinologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Diagnosis of ONE of the following: (1) growth hormone gene deletion who have developed neutralizing antibodies to growth hormone OR (2) Severe primary IGF-1 deficiency and ALL of the following (a) height standard deviation score less than or equal to -3.0 AND (b) basal IGF-1 standard deviation score less than or equal to -3.0 AND normal or elevated growth hormone<br>CONTINUATION OF INCRELEX: documentation of increase in growth velocity from baseline AND annual clinical re-evaluation by the treating endocrinologist |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# INGREZZA

## Products Affected

- INGREZZA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by a neurologist or a psychiatrist  |
| <b>Coverage Duration</b>            | Initial authorization: 3 months, Reauthorization: indefinite   |
| <b>Other Criteria</b>               | ALL of the following (1) Diagnosis of moderate to severe tardive dyskinesia (2) documentation of baseline AIMS and (3) one of the following: (a) persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, or (b) member is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Reauthorization criteria: Valbenazine (Ingrezza) is reapproved with documentation of positive clinical response, as demonstrated by improvement in AIMS, to Ingrezza therapy |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# INHALED TOBRAMYCIN

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## Products Affected

- TOBI PODHALER

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | 6 years of age or older   |
| Prescriber Restrictions      | Prescribed by or in consultation with a pulmonologist OR infectious disease specialist. |
| Coverage Duration            | Indefinite  |
| Other Criteria               | (1) diagnosis of cystic fibrosis AND (2) evidence of P. aeruginosa in the lungs         |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# INJECTABLE METHOTREXATE

## Products Affected

- OTREXUP SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.4ML, 12.5 MG/0.4ML, 15 MG/0.4ML, 17.5 MG/0.4ML, 20 MG/0.4ML, 22.5 MG/0.4ML, 25 MG/0.4ML
- RASUVO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.2ML, 12.5 MG/0.25ML, 15 MG/0.3ML, 17.5 MG/0.35ML, 20 MG/0.4ML, 22.5 MG/0.45ML, 25 MG/0.5ML, 30 MG/0.6ML, 7.5 MG/0.15ML

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | Psoriasis: deny if less than 18 years   |
| <b>Prescriber Restrictions</b>      | RA and pJIA: Recommended by rheumatologist. Psoriasis: recommended by dermatologist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Injectable Methotrexate is approved when ONE of the following is met: (1) Diagnosis of severe, active rheumatoid arthritis (RA), psoriatic arthritis or polyarticular juvenile idiopathic arthritis (pJIA) and inadequate response or inability to tolerate oral methotrexate OR (2) diagnosis of severe psoriasis and an inadequate response to BOTH of the following (a) oral methotrexate AND (b) topical steroids (e.g. clobetasol propionate cream/ointment, betamethasone cream/ointment, etc.) |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# INTRAVENOUS IMMUNE GLOBULIN (IVIG)

## Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 5 GM/50ML
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML
- PANZYGA
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML

| PA Criteria                  | Criteria Details |
|------------------------------|------------------|
| Exclusion Criteria           |                  |
| Required Medical Information |                  |
| Age Restrictions             |                  |
| Prescriber Restrictions      |                  |
| Coverage Duration            | 6 months         |

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| <b>Other Criteria</b> | <p>Subject to Part B vs Part D review. Part D is medically necessary when ONE of the following is present (1) autoimmune mucocutaneous blistering disease pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid , benign mucous membrane pemphigoid, epidermolysis bullosa acquisita and ONE of the following: (a) inadequate response or inability to tolerate conventional therapy (i.e. steroids, immunosuppressants) OR (b) rapidly progressive disease in conjunction with conventional therapy (i.e. steroids, immunosuppressants) (2) acute idiopathic thrombocytopenia purpura (ITP) and ONE of the following (a) management of acute bleeding (b) used to increase platelet count prior to surgical procedures) (c) severe thrombocytopenia (platelets less than 20, 000 per uL) or (d) high risk for intracerebral hemorrhage (3) chronic ITP and ALL of the following (a) inadequate response or inability to tolerate corticosteroids (b) duration of illness greater than 6 months (c) platelets persistently less than 20,000/ uL (4) chronic B-cell lymphocytic leukemia with IgG less than 600mg/dL and recurrent, serious bacterial infections requiring antibiotic therapy (5) hematopoietic stem cell transplant and IgG less than 400mg/dL (6) HIV and all of the following (a) less than 14 years of age (b) evidence of qualitative or quantitative humoral immunologic defects and (c) current bacterial infection despite antimicrobial prophylaxis (7) solid organ transplant (8) chronic inflammatory demyelinating polyneuritis confirmed by electrodiagnostic testing or nerve biopsy and an inadequate response or inability to tolerate corticosteroids (9) dermatomyositis or polymyositis diagnosed by laboratory testing (antinuclear or myositis specific antibodies), biopsy, EMG, or MRI) and inadequate response or inability to tolerate steroids or immunosuppressants (10) Guillain Barre syndrome with impaired function (i.e. unable to stand or walk without aid) (11) Lambert Eaton myasthenic syndrome refractory to steroids, immunosuppressants, or cholinesterase inhibitors (12) multifocal motor neuropathy diagnosed by electrodiagnostic studies (13) acute exacerbations of MS unresponsive to steroids (14) myasthenia gravis refractory to at least 8 weeks of standard therapy (steroids, immunosuppressants, cholinesterase inhibitors) (15) myasthenic crisis (16) stiff person syndrome refractory to standard therapy (muscle relaxants, benzodiazepines, gabapentin) (17) severe, active SLE unresponsive to steroids (18) Kawasaki disease CONTINUATION OF THERAPY CRITERIA:</p> |
|                       | Documentation of clinical improvement as appropriate to the diagnosis such as, but not limited to, Rankin score and Activities of Daily Living (ADL) scores.   |
| <b>Indications</b>    | All Medically-accepted Indications.  |
| <b>Off Label Uses</b> |  |

# ISTURISA

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## Products Affected

- ISTURISA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Cushing's disease (CD): (1) Diagnosis of (pituitary) Cushing's disease. (2) Pituitary surgery is not an option or has not been curative (3) Member has inadequate response or inability to tolerate Signifor [LAR]. |
| <b>Age Restrictions</b>             | (CD): Member is 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | (CD): Prescribed by or in consultation with an endocrinologist  |
| <b>Coverage Duration</b>            | (CD): Remainder of contract year  |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# JYNARQUE

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## Products Affected

- JYNARQUE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Baseline serum transaminases and bilirubin prior to initiation of therapy  |
| Age Restrictions             | Deny if less than 18 years of age  |
| Prescriber Restrictions      | Prescribed by a nephrologist or kidney transplant specialist   |
| Coverage Duration            | 3 months for initial and 12 months for re-authorization  |
| Other Criteria               | RE-AUTHORIZATION: ALL of the following (1) ONE of the following (a) decline in kidney function has slowed or (b) kidney pain has improved and (2) serum transaminase less than 3 times the upper limit of normal and (3) bilirubin less than 2 times upper limit of normal |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# KALYDECO

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## Products Affected

- KALYDECO

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Mutation was documented by an FDA-cleared CF to detect the presence of the CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions |
| <b>Age Restrictions</b>             | Patient is 6 months of age or older for granules. Patient is 6 years of age or older for tablets  |
| <b>Prescriber Restrictions</b>      | Prescriber is a pulmonologist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Diagnosis of Cystic Fibrosis with documentation of one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data                                       |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# KEVEYIS

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## Products Affected

- KEVEYIS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concomitant use of high dose Aspirin, severe pulmonary disease and hepatic insufficiency                            |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by a neurologist   |
| <b>Coverage Duration</b>            | Initial criteria: 3 months Reauthorization: indefinite  |
| <b>Other Criteria</b>               | Reauthorization Criteria: Dichlorphenamide (Keveyis) is reapproved with documentation of positive clinical response |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# KEVZARA

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## Products Affected

- KEVZARA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of live vaccines prior to start of therapy                                  |
| <b>Age Restrictions</b>             | Deny if less than 18 years  |
| <b>Prescriber Restrictions</b>      | Prescribed by rheumatologist  |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Rheumatoid arthritis: BOTH of the following (1) inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# KINERET

## Products Affected

- KINERET SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB)  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by rheumatologist or pediatric specialist  |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | For diagnosis of Rheumatoid Arthritis or Juvenile idiopathic arthritis: inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel). For diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID): diagnosis has been confirmed by one of the following: NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR evidence of active inflammation including both of the following: clinical symptoms (e.g., rash, fever, arthralgia) and elevated acute phase reactants (e.g., ESR, CRP). |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# KORLYM

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## Products Affected

- KORLYM

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | Pregnancy   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Prescribed by an endocrinologist  |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Documentation of ALL of the following: (1) hyperglycemia secondary to hypercortisolism in adult patient with endogenous Cushing syndrome, (2) patient has type 2 diabetes mellitus or glucose intolerance AND (3) patient has failed surgery or is not a candidate for surgery. |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# LIDOCAINE TRANSDERMAL PATCH

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## Products Affected

- *lidocaine external patch 5 %*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | Indefinite   |
| Other Criteria               | Documentation of post-herpetic neuralgia or diabetic peripheral neuropathy |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# MULPLETA

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## Products Affected

- MULPLETA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Documentation of baseline platelet count less than 50,000/mcL |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 1 month   |
| Other Criteria               |   |
| Indications                  | All Medically-accepted Indications.                           |
| Off Label Uses               |   |

# MYALEPT

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## Products Affected

- MYALEPT

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescribed by an endocrinologist                               |
| Coverage Duration            | Indefinite   |
| Other Criteria               | Diagnosis of congenital or acquired generalized lipodystrophy. |
| Indications                  | All Medically-accepted Indications.                            |
| Off Label Uses               |  |

# NATPARA

## Products Affected

- NATPARA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if age less than 18 years   |
| <b>Prescriber Restrictions</b>      | Prescribed by an endocrinologist   |
| <b>Coverage Duration</b>            | Initial authorization: 6 month, Re-authorization: until the end of the contract year   |
| <b>Other Criteria</b>               | Documentation of the following: Diagnosis of hypocalcemia due to chronic hypoparathyroidism. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. NATPARA will be used as an adjunct treatment. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# NAYZILAM

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## Products Affected

- NAYZILAM

| PA Criteria                  | Criteria Details                                |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Prescriber is a neurologist/epilepsy specialist |
| Coverage Duration            | Indefinite                                      |
| Other Criteria               |   |
| Indications                  | All Medically-accepted Indications.             |
| Off Label Uses               |   |

# NEXLETOL/NEXLIZET

## Products Affected

- NEXLETOL
- NEXLIZET

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Heterozygous Familial Hypercholesterolemia (HeFH) OR Atherosclerotic Cardiovascular Disease (ASCVD) (Initial): (1) One of the following: (A) Diagnosis of HeFH, OR (B) Diagnosis of ASCVD as diagnosed by either stress test, angiography, atherosclerotic event (e.g. MI, angina, stroke, claudication, carotid stenosis) or arterial intervention for atherosclerotic disease (e.g. coronary, peripheral, carotid). (2) ONE of the following: (A) LDL-C 70 mg/dL or greater after at least 8 weeks of one low, moderate or high-intensity statin therapy and member will continue to receive statin therapy at maximally tolerated dose OR (B) Inability to tolerate statin therapy as documented by one of the following: (i) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (ii) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN) or (iii) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (iv) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks. (3) One of the following: (A) Member has been receiving at least 8 weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy OR (B) Member has contraindication or intolerance to ezetimibe (Zetia). |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | (HeFH, ASCVD) (Initial): 6 months. (HeFH, ASCVD) (Continuation): 12 months  |
| <b>Other Criteria</b>               | (HeFH, ASCVD) (Continuation): (1) Positive clinical response to therapy (e.g., reduction in LDL-C levels), (2) One of the following: (A) Member continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose OR (B) Member has inability to tolerate other lipid-lowering therapy (e.g., statins, ezetimibe)  |
| <b>Indications</b>                  | All Medically-accepted Indications.   |

| PA Criteria    | Criteria Details |
|----------------|------------------|
| Off Label Uses |                  |

# NON ORAL PAH AGENTS

## Products Affected

- VENTAVIS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by Cardiologist or Pulmonologist   |
| <b>Coverage Duration</b>            | 6 months for initial approvals and 12 months for Continuation approvals   |
| <b>Other Criteria</b>               | Subject to Part B vs Part D review. Part D is medically necessary when ALL of the following are met: (1) Documentation of a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography (3) Documentation of mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion, CONTINUATION OF THERAPY: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# NON-ORAL ANTIBIOTICS

## Products Affected

- NUZYRA
- SIVEXTRO
- ZEMDRI

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Deny if not prescribed by an infectious disease (ID) specialist or prescribed with ID consultation (telephone consultation is acceptable) including name of the ID specialist and date of the consultation within the last 60 days  |
| <b>Coverage Duration</b>            | 1 month   |
| <b>Other Criteria</b>               | Subject to Part B vs Part D review. Part D is medically necessary when documentation of a current bacterial infection and an inadequate response or inability to tolerate at least TWO drugs to which the organism is susceptible OR the requested agent is the only antibiotic to which the organism is susceptible. RE-AUTHORIZATION CRITERIA: Documentation that an infectious disease consult determines that a longer duration of therapy is required. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# NON-ORAL CHEMO AGENTS

## Products Affected

- SYNRIBO
- TRELSTAR MIXJECT

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by an oncologist/hematologist.   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Subject to Part B vs Part D review. Part D is medically necessary when ANY of the following inclusion criteria is met: (1) Drug is FDA approved for indication and regimen requested, (2) The indication and regimen is classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, (3) narrative text in The American Hospital Formulary Service-Drug Information (AHFS-DI) or Clinical Pharmacology Compendium is supportive for the specific condition(s) requested, (4) The Micromedex Compendium and the strength of recommendation is listed as Class I, Class IIa, or Class IIb for the specific condition(s) requested, (5) Indication is listed in Lexi-Drugs as "off label" with evidence level A, (6) supported by Peer-Reviewed Medical Literature as defined in Chapter 15 Section 50.4.5 of the Medicare Benefit Policy Manual, (7) Documentation of continuous therapy with the medication requested. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# NON-PREFERRED HEPATITIS C AGENTS

## Products Affected

- SOVALDI ORAL PACKET
- SOVALDI ORAL TABLET 400 MG
- VIEKIRA PAK
- VOSEVI
- ZEPATIER

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Hepatitis C Genotype   |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Duration will be applied consistent with AASLD/ IDSA guidance  |
| <b>Other Criteria</b>               | BOTH of the following (1) criteria will be applied consistent with current AASLD/ IDSA guidance and (2) inability to tolerate Harvoni or Eplclusa or Mavyret where indicated |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# NOURIANZ

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## Products Affected

- NOURIANZ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information | Documentation is provided of ALL of the following: (1) Diagnosis of Parkinson's disease (2) concurrent use of carbidopa/levodopa containing product, (3) Member is experiencing intermittent OFF episodes, (4) member had inadequate response or inability to tolerate ONE of the following: (a) MAO-B inhibitor (e.g., rasagiline, selegiline), (b) Dopamine agonist (e.g., pramipexole, ropinirole), (c) COMT inhibitor (e.g., entacapone) |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescribed by or in consultation with a neurologist  |
| Coverage Duration            | Indefinite   |
| Other Criteria               |  |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# NOXAFIL

## Products Affected

- NOXAFIL ORAL
- *posaconazole*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             | Deny if less than 13 years  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an infectious disease specialist or as part of chemotherapy prophylaxis protocol  |
| <b>Coverage Duration</b>            | Remainder of contract year  |
| <b>Other Criteria</b>               | Documentation of either of the following (1) for use in prophylaxis of invasive Aspergillus and Candida infections due to being severely immunocompromised after inadequate response or inability to tolerate voriconazole (Vfend) OR (2) for a diagnosis of oropharyngeal candidiasis after inadequate response or inability to tolerate both itraconazole and fluconazole |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# NUCALA

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## Products Affected

- NUCALA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | Patient is 6 years of age or older  |
| Prescriber Restrictions      | Severe Asthma: Prescribed by or in consultation with pulmonologist or allergy/immunology specialist. Eosinophilic granulomatosis with polyangiitis: Prescribed by or in consultation with a rheumatologist. |
| Coverage Duration            | 12 months for Initial and Re-authorization criteria   |

| PA Criteria           | Criteria Details  |
|-----------------------|---|
| <b>Other Criteria</b> | <p>Subject to Part B vs Part D review. Part D is medically necessary when there is documentation of ONE of the following: 1) Diagnosis of severe asthma with eosinophilic phenotype as defined by one of the following: a) blood eosinophil levels are at least 150 cells/microliter at initiation of therapy (measured within 6 weeks of dosing), or b) blood eosinophil levels at least 300 cells/microliter within the past 12 months. 2) Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months OR patient has had any prior intubation for an asthma exacerbation OR Patient has had a prior asthma-related hospitalization within the past 12 months, AND 3) Patient is currently treated with high-dose inhaled corticosteroids (ICS) (e.g., greater than or equal to 500 mcg fluticasone propionate equivalent/day) AND an additional controller medication (e.g., long-acting beta agonist such as salmeterol or formoterol, leukotriene inhibitor such as montelukast, theophylline), unless the individual is intolerant of or has a contraindication to two of the additional controller agents, OR II) Diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) and ALL of the following: (1) Member's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy), and (2) Member is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone). Reauthorization criteria: For Diagnosis of severe asthma: Patient is currently treated with high-dose inhaled corticosteroids (ICS) (e.g., greater than or equal to 500mcg fluticasone propionate equivalent/day) AND an additional controller medication (e.g., long-acting beta agonist such as salmeterol or formoterol, leukotriene inhibitor such as montelukast, theophylline), unless the individual is intolerant of or has a contraindication to two of the additional controller agents. For Diagnosis of EGPA: Documentation of positive clinical response to therapy (e.g., increase in remission time)</p> |
| <b>Indications</b>    | All Medically-accepted Indications.   |
| <b>Off Label Uses</b> |   |

# NUEDEXTA

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## Products Affected

- NUEDEXTA

| PA Criteria                  | Criteria Details                     |
|------------------------------|--------------------------------------|
| Exclusion Criteria           |                                      |
| Required Medical Information |                                      |
| Age Restrictions             | Deny if less than 18 years           |
| Prescriber Restrictions      |                                      |
| Coverage Duration            | Indefinite                           |
| Other Criteria               | Documentation of Pseudobulbar affect |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |                                      |

# NUPLAZID

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Documentation of inadequate response or inability to tolerate ONE of the following (1) quetiapine or (2) clozapine. |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# OCALIVA

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## Products Affected

- OCALIVA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Prescribed by hepatologist or gastroenterologist  |
| Coverage Duration            | Initial authorization is 6 months and Reauthorization=Indefinite                                |
| Other Criteria               | Reauthorization is approved with documentation of positive clinical response to Ocaliva therapy |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# OLUMIANT

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## Products Affected

- OLUMIANT

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB)   |
| <b>Age Restrictions</b>             | Deny if less than 18 years of age  |
| <b>Prescriber Restrictions</b>      | Prescribed by a rheumatologist   |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (1) Inadequate response or inability to tolerate to BOTH of the following: (a) ONE of the following: Humira or Enbrel, AND (b) ONE of the following: Rinvoq or Xeljanz/Xeljanz XR or (2) documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# ORAL ANTIBIOTICS

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## Products Affected

- NUZYRA
- SIVEXTRO
- XENLETA ORAL

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Deny if not prescribed by an infectious disease (ID) specialist or prescribed with ID consultation (telephone consultation is acceptable) including name of the ID specialist and date of the consultation within the last 60 days   |
| <b>Coverage Duration</b>            | 1 month  |
| <b>Other Criteria</b>               | Documentation of a current bacterial infection and an inadequate response or inability to tolerate TWO antibiotics to which the organism is susceptible OR the requested medication is the only antibiotic to which the organism is susceptible. RE-AUTHORIZATION CRITERIA: Documentation that an infectious disease consult determines that a longer duration of therapy is required. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# ORAL CHEMO AGENTS

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## Products Affected

- *abiraterone acetate*
- AFINITOR
- AFINITOR DISPERZ
- ALECENSA
- ALUNBRIG
- AYVAKIT
- BALVERSA
- *bexarotene*
- BOSULIF
- BRAFTOVI ORAL CAPSULE 75 MG
- BRUKINSA
- CABOMETYX
- CALQUENCE
- CAPRELSA
- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)
- COPIKTRA
- COTELLIC
- DAURISMO
- ERIVEDGE
- ERLEADA
- *erlotinib hcl*
- *everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg*
- FARYDAK ORAL CAPSULE 10 MG, 20 MG
- GAVRETO
- GILOTRIF
- GLEOSTINE ORAL CAPSULE 10 MG, 100 MG, 40 MG
- IBRANCE
- ICLUSIG
- IDHIFA
- *imatinib mesylate*
- IMBRUVICA
- INLYTA
- INQOVI
- INREBIC
- IRESSA
- JAKAFI
- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)
- KISQALI FEMARA(200 MG DOSE)
- KOSELUGO
- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)
- LONSURF
- LORBRENA
- LYNPARZA ORAL TABLET
- MEKINIST
- MEKTOVI
- NERLYNX
- NEXAVAR
- NINLARO
- NUBEQA
- ODOMZO
- PEMAZYRE
- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)
- POMALYST
- QINLOCK
- RETEVMO
- REVLIMID
- ROZLYTREK
- RUBRACA
- RYDAPT
- SPRYCEL
- STIVARGA
- SUTENT
- TABRECTA
- TAFINLAR
- TAGRISSO
- TALZENNA
- TARCEVA
- TASIGNA

- TAZVERIK
- THALOMID
- TIBSOVO
- TUKYSA
- TURALIO
- TYKERB
- VENCLEXTA
- VENCLEXTA STARTING PACK
- VERZENIO
- VITRAKVI
- VIZIMPRO
- VOTRIENT
- XALKORI
- XOSPATA
- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)
- XTANDI
- YONSA
- ZEJULA
- ZELBORAF
- ZOLINZA
- ZYDELIG
- ZYKADIA ORAL TABLET
- ZYTIGA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Approved when ANY of the following inclusion criteria is met: (1) Drug is FDA approved for indication and regimen requested, (2) The indication and regimen is classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, (3) narrative text in The American Hospital Formulary Service-Drug Information (AHFS-DI) or Clinical Pharmacology Compendium is supportive for the specific condition(s) requested, (4) The Micromedex Compendium and the strength of recommendation is listed as Class I, Class IIa, or Class IIb for the specific condition(s) requested, (5) Indication is listed in Lexi-Drugs as "off label" with evidence level A, (6) supported by Peer-Reviewed Medical Literature as defined in Chapter 15 Section 50.4.5 of the Medicare Benefit Policy Manual, (7) Documentation of continuous therapy with the medication requested. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# ORAL PAH AGENTS

## Products Affected

- *ambrisentan*
- *bosentan*
- LETAIRIS
- OPSUMIT
- ORENITRAM
- TRACLEER

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescriber is a Cardiologist or Pulmonologist  |
| <b>Coverage Duration</b>            | 6 month for initial authorization and 12 months for continuation approvals   |
| <b>Other Criteria</b>               | Approved when all of the following inclusion criteria are met: (1) Documentation of a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV, (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography AND (3) Documentation of mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion. Continuation of therapy: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# ORENCIA SQ

## Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to start of therapy.   |
| <b>Age Restrictions</b>             | Deny if less than 2 years   |
| <b>Prescriber Restrictions</b>      | RA, JIA: Prescriber is a rheumatologist, PsA: Prescriber is a dermatologist or rheumatologist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | ONE of the following: (1) For adult rheumatoid arthritis: inadequate response or inability to tolerate to TWO of the following: (a) Humira, (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR OR documentation demonstrating that a trial may be inappropriate, (2) For psoriatic arthritis: inadequate response or inability to tolerate to TWO of the following: (a) Humira, (b) Enbrel, (c) Xeljanz/Xeljanz XR OR documentation demonstrating that a trial may be inappropriate, or (3) For juvenile idiopathic arthritis: documentation of either inadequate response or inability to tolerate adalimumab (Humira) and etanercept (Enbrel) OR documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# ORILISSA

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## Products Affected

- ORILISSA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | 24 months for 150mg tablet, 6 months for 200mg tablet  |
| Other Criteria               | Documentation is provided of BOTH of the following: (1) Documentation of ONE of the following, a) Inadequate response or inability to tolerate BOTH of the following (i) one nonsteroidal anti-inflammatory drug AND (ii) (a) one contraceptive OR (b) Member has had surgical ablation to prevent recurrence, (2) Treatment duration does not exceed 24 months (150mg tablet) or 6 months (200mg tablet). |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# ORKAMBI

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## Products Affected

- ORKAMBI

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Diagnosis of CF other than those homozygous for the F508del mutation   |
| <b>Required Medical Information</b> | If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene |
| <b>Age Restrictions</b>             | Deny if age is less than 2 years   |
| <b>Prescriber Restrictions</b>      | Prescriber is a pulmonologist  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ALL of the following: (1) Diagnosis of Cystic Fibrosis, (2) Patient is homozygous for the F508del mutation in the CFTR gene                         |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# OTEZLA

## Products Affected

- OTEZLA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if less than 18 years   |
| <b>Prescriber Restrictions</b>      | Recommended by Rheumatologist or Dermatologist   |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (1) BOTH of the following (a) diagnosis of oral ulcers associated with Behcet's disease (BD), and (b) Inadequate response or inability to tolerate topical oral corticosteroids AND systemic corticosteroids OR (2) diagnosis of psoriatic arthritis and an inadequate response or inability to tolerate to TWO of the following: (a) Humira, (b) Enbrel, (c) Xeljanz/Xeljanz XR OR documentation demonstrating that a trial may be inappropriate, or (3) plaque psoriasis AND an inadequate response or inability to tolerate to BOTH of the following: (a) ONE of the following: (i) Humira, (ii) Enbrel, or (iii) Skyrizi AND (b) Cosentyx OR documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# OXBRYTA

## Products Affected

- OXBRYTA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | (Initial, Reauth): Concurrent therapy with Adakveo (crizanlizumab-tmca)  |
| <b>Required Medical Information</b> | Sickle Cell Disease (SCD)(Initial): (1) Diagnosis of sickle cell disease (2) Patient had at least 1 vaso-occlusive crisis (VOC) event within the past 12 months (e.g., acute painful crisis, acute chest syndrome) (3) Hemoglobin level that is between 5.5 g/dL and 10.5 g/dL prior to therapy initiation (4) Inadequate response or inability to tolerate hydroxyurea (i.e., Siklos, Droxia) |
| <b>Age Restrictions</b>             | (SCD)(Initial, Reauth):Patient is 12 years of age or greater   |
| <b>Prescriber Restrictions</b>      | (SCD)(Initial, Reauth):Prescribed by or in consultation with a hematologist  |
| <b>Coverage Duration</b>            | (SCD):(Initial/Reauth): 12 months  |
| <b>Other Criteria</b>               | (SCD)(Reauth): Patient has had a positive clinical response to Oxbryta therapy (e.g., an increase in hemoglobin level of greater than or equal to 1 g/dL from baseline, decreased annualized incidence rate of VOC)  |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# OXERVATE

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## Products Affected

- OXERVATE

| PA Criteria                  | Criteria Details                             |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Deny if not prescribed by an ophthalmologist |
| Coverage Duration            | 8 weeks                                      |
| Other Criteria               |  |
| Indications                  | All Medically-accepted Indications.          |
| Off Label Uses               |  |

# PALYNZIQ

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## Products Affected

- PALYNZIQ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information | Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.   |
| Age Restrictions             | Deny if less than 18 years of age   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Initial: 6 months, Continuation: Indefinite   |
| Other Criteria               | CONTINUATION CRITERIA: Documentation of a positive clinical response to Palynziq therapy defined by at least a 20% reduction in blood phenylalanine concentrations from pre-treatment baseline OR blood phenylalanine concentrations less than or equal to 600 micromol/L |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# PARATHYROID HORMONE ANALOGS

## Products Affected

- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR
- *teriparatide (recombinant)*
- TYMLOS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Any of the following: (1) history of Paget's disease of the bone (2) history of bone cancer or other cancers that have metastasized to the bone (3) Skeletal malignancies or other metabolic bone disease besides osteoporosis (4) Preexisting hypercalcemia (5) Pregnant or nursing women (6) unexplained elevations of alkaline phosphatase (7) open epiphyses (8) history of external beam or implant radiation therapy involving the skeleton   |
| <b>Required Medical Information</b> | Osteoporosis defined as T score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR history of osteoporotic fracture (i.e. hip, spine, etc.). Glucocorticoid induced osteoporosis in men or women defined as daily dose greater than or equal to 5mg prednisone or equivalent for at least 3 months   |
| <b>Age Restrictions</b>             | Deny if less than 18 years  |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Remainder of contract year  |
| <b>Other Criteria</b>               | ONE of the following: (1) Diagnosis of Primary or hypogonadal osteoporosis in men with inadequate response or inability to tolerate at least one of the following (a) bisphosphonates, (b) hormone replacement therapy, (c) selective-estrogen receptor modulators (SERMs). (2) Diagnosis of postmenopausal osteoporosis, member has had an Inadequate response or inability to tolerate BOTH of the following: (a) at least one of the following (i) bisphosphonates, (ii) hormone replacement therapy, (iii) selective-estrogen receptor modulators (SERMs), AND (b) Denosumab (Prolia) (3) diagnosis of Glucocorticoid- induced osteoporosis in men or women, member has had an Inadequate response or inability to tolerate BOTH of the following: (a) at least one of the following (i) bisphosphonates, (ii) hormone replacement therapy, (iii) selective-estrogen receptor modulators (SERMs), AND (b) Denosumab (Prolia) Reauthorization criteria: documentation that cumulative lifetime therapy does not exceed 2 years |

| PA Criteria           | Criteria Details                    |
|-----------------------|-------------------------------------|
| <b>Indications</b>    | All Medically-accepted Indications. |
| <b>Off Label Uses</b> |                                     |

## PART D VS EXCLUDED

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### Products Affected

- AURYXIA
- INTRAROSA
- OSPHENA

| PA Criteria                  | Criteria Details                    |
|------------------------------|-------------------------------------|
| Exclusion Criteria           |                                     |
| Required Medical Information |                                     |
| Age Restrictions             |                                     |
| Prescriber Restrictions      |                                     |
| Coverage Duration            | Indefinite                          |
| Other Criteria               |                                     |
| Indications                  | All Medically-accepted Indications. |
| Off Label Uses               |                                     |

## PDE INHIBITOR AGENTS FOR PAH

### Products Affected

- ADCIRCA
- ALYQ
- REVATIO ORAL SUSPENSION RECONSTITUTED
- *tadalafil (pah)*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Deny if not prescribed by Cardiologist or Pulmonologist  |
| <b>Coverage Duration</b>            | 6 months for initial approvals and 12 months for renewals  |
| <b>Other Criteria</b>               | Documentation of ALL of the following: (1) Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV, (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography, (3) Mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion. (4) inadequate response or inability to tolerate sildenafil<br>RE-AUTHORIZATION CRITERIA: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# PRALUENT

## Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | 6 months Continuation 12 months  |
| <b>Other Criteria</b>               | <p>INITIAL AUTHORIZATION: Diagnosis of either hyperlipidemia or atherosclerotic cardiovascular disease (ASCVD) as diagnosed by either stress test, angiography, atherosclerotic event (e.g. MI, angina, stroke, claudication, carotid stenosis) or arterial intervention for atherosclerotic disease (e.g. coronary, peripheral, carotid) AND ONE of the following: (1) LDL-C 70 mg/dL or greater after a minimum 8-week trial of at least moderate-intensity statin therapy OR (2) Inability to tolerate statin therapy as documented by one of the following: (a) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (b) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN or (c) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (d) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks</p> <p>CONTINUATION OF PRALUENT: documentation of sustained reduction in LDL-C from baseline as defined by 25% reduction of LDL-C from baseline or sustained below 70 mg/dL.</p> |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# PREFERRED HEPATITIS C AGENTS

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## Products Affected

- EPCLUSA ORAL TABLET 400-100 MG
- HARVONI ORAL PACKET
- HARVONI ORAL TABLET 90-400 MG
- *ledipasvir-sofosbuvir*
- MAVYRET
- *sofosbuvir-velpatasvir*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Hepatitis C Genotype  |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Duration will be applied consistent with AASLD/ IDSA guidance         |
| <b>Other Criteria</b>               | Criteria will be applied consistent with current AASLD/ IDSA guidance |
| <b>Indications</b>                  | All Medically-accepted Indications.                                   |
| <b>Off Label Uses</b>               |   |

# PRETOMANID

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## Products Affected

- *pretomanid*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Multidrug Resistant Tuberculosis (MDRTB): (1) Diagnosis of pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive MDRTB. (2) Medication will be used as part of a combination regimen with bedaquiline (Sirturo®) and linezolid. |
| <b>Age Restrictions</b>             | (MDRTB): Member is 18 years of age or older   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | (MDRTB): 26 weeks   |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# PROCYSBI

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## Products Affected

- PROCYSBI ORAL PACKET

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Hypersensitivity to penicillamine  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescriber is a nephrologist.  |
| Coverage Duration            | 3 months for initial authorization and 6 months for renewal authorization  |
| Other Criteria               | Diagnosis of nephrotic cystinosis AND documentation of inadequate response or titration from cysteamine bitartrate immediate-release capsules (Cystagon) AND documentation of baseline WBC and alkaline phosphatase levels. REAUTHORIZATION CRITERIA: Documentation of monitoring ALL of the following at least ONCE since previous authorization (1) ONE of the following: (a) WBC cysteine level or (b) plasma cysteamine level (2) WBC count AND (3) alkaline phosphatase level |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# PROLIA

## Products Affected

- PROLIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Subject to Part B vs Part D review. Part D is medically necessary for the treatment OSTEOPOROSIS when BOTH of the following are met: (1) ONE of the following: (a) T-score less than or equal to -2.5 (b) history of osteoporotic fracture (e.g., vertebral, hip, non-vertebral) or (c) multiple risk factors for fracture, AND (2) ONE of the following: (a) inadequate response or inability to tolerate at least one other osteoporosis medicine (e.g., oral bisphosphonates, calcitonin, estrogens, selective estrogen receptor modulator (SERMs)) or (b) severely deteriorated condition indicating that the osteoporosis is so significant that a trial of oral bisphosphonates is not medically warranted. For the treatment of OSTEOPENIA: (T-score less than -1.0, but greater than -2.5), with ONE of the following: (a) receiving adjuvant aromatase inhibitor therapy for breast cancer or (b) receiving androgen deprivation therapy for non-metastatic prostate cancer. |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# PULMONARY FIBROSIS AGENTS

## Products Affected

- ESBRIET
- OFEV

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by a pulmonologist or lung transplant specialist  |
| <b>Coverage Duration</b>            | 12 months initial and reauthorization  |
| <b>Other Criteria</b>               | Idiopathic Pulmonary Fibrosis (IPF) (Initial): Diagnosis of IPF confirmed by high resolution CT scan or biopsy. Systemic sclerosis-associated interstitial lung disease (SScILD): confirmed by a high resolution CT scan or biopsy. Chronic Fibrosing Interstitial Lung Disease (ILDs) with progressive phenotype (Initial): (1) Confirmed by high resolution CT (HRCT) showing at least 10% of lung volume with fibrotic features, (2) Disease has a progressive phenotype as observed by one of the following: (a) decline of forced vital capacity (FVC), (b) worsening of respiratory symptoms, (c) increased extent of fibrosis seen on imaging. REAUTHORIZATION CRITERIA (IPF, ILDs and SSc-ILD): BOTH of the following (1) stabilization from baseline or a less than 10% decline in forced vital capacity AND (2) no elevations in AST or ALT greater than 5 times upper limit of normal or greater than 3 times upper limit of normal with signs or symptoms of severe liver damage |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# QBREXZA

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## Products Affected

- QBREXZA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Deny if less than 9 years of age   |
| Prescriber Restrictions      | Deny if not prescribed by or in consultation with a dermatologist  |
| Coverage Duration            | Indefinite   |
| Other Criteria               | BOTH of the following: (1) hyperhidrosis has persisted for at least 6 months (2) Hyperhidrosis Disease Severity Scale grade 3 or 4 |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# QUALAQUIN

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## Products Affected

- *quinine sulfate oral*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      |  |
| Coverage Duration            | For Babesiosis: 7 days For Uncomplicated Malaria 14 Days   |
| Other Criteria               | ONE of the following: (1) Diagnosis of uncomplicated malaria due to (a) plasmodium falciparum malaria or (b) plasmodium vivax OR (2) Diagnosis of Babesiosis |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# RAVICTI

## Products Affected

- RAVICTI

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Acute hyperammonemia. N-acetylglutamate synthase (NAGS) deficiency   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if less than age 2 months   |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Remainder of contract year   |
| <b>Other Criteria</b>               | Documentation of BOTH of the following: (1) diagnosis of urea cycle disorder involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamoylase (OTC), or argininosuccinic acid synthetase (AAS) confirmed via enzymatic, biochemical, or genetic testing, (2) inadequate response or inability to tolerate sodium phenylbutyrate |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      |   |
| <b>Coverage Duration</b>            | Initial Authorization: 6 months Continuation: 12 months   |
| <b>Other Criteria</b>               | INITIAL AUTHORIZATION: Diagnosis of either hyperlipidemia, homozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease (ASCVD) as diagnosed by either stress test, angiography, atherosclerotic event (e.g. MI, angina, stroke, claudication, carotid stenosis) or arterial intervention for atherosclerotic disease (e.g. coronary, peripheral, carotid) AND ONE of the following: (1) LDL-C 70 mg/dL or greater after a minimum 8-week trial of at least moderate-intensity statin therapy OR (2) Inability to tolerate statin therapy as documented by one of the following: (a) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (b) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN or (c) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (d) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks. CONTINUATION OF REPATHA: approved for 12 months if there is documentation of sustained reduction in LDL-C from baseline as defined by 25% reduction of LDL-C from baseline or sustained below 70 mg/dL. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# RESPIRATORY ENZYMES

## Products Affected

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION
- RECONSTITUTED ZEMAIRA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | IgA deficiency with known anti-IgA antibody  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Subject to Part B vs Part D review and if part D is medically necessary when BOTH of the following are met: (1) low serum concentration of alpha-1 antitrypsin defined as less than 35 percent of normal (less than 80 mg/dL or less than 11 uM/L or less than 0.8 g/L) (2) the individual has progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV 1) |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# RINVOQ

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## Products Affected

- RINVOQ

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). Not used in combination with any other biologic disease modifying anti-rheumatic drug (DMARD), other JAK inhibitors, or potent immunosuppressants |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | (Initial) Prescribed by or in consultation with a rheumatologist  |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Diagnosis of moderate to severely active rheumatoid arthritis. Member has inadequate response or inability to tolerate methotrexate.  |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# RUZURGI

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## Products Affected

- RUZURGI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Patient is 6 to less than 17 years of age.   |
| Prescriber Restrictions      | Prescribed by or in consultation with a neurologist  |
| Coverage Duration            | 90 days, indefinite for continuation   |
| Other Criteria               | INITIAL CRITERIA: Both of the following: (1) Neurological symptoms persist after treatment of malignancy, when malignancy is present and (2) Documentation the member has moderate to severe weakness.<br>CONTINUATION CRITERIA: Documentation is provided of a positive clinical response to therapy. |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# SAMSCA

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## Products Affected

- SAMSCA
- *tolvaptan oral tablet 30 mg*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | (1) patients who are unable to sense or appropriately respond to thirst, hypovolemic hyponatremia (2) concomitant use of strong CYP3A inhibitors |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if less than 18 years   |
| <b>Prescriber Restrictions</b>      | Prescribed by cardiologist, endocrinologist or nephrologist  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of a diagnosis of clinically significant hypervolemic or euvolemic hyponatremia.   |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# SEROSTIM

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## Products Affected

- SEROSTIM SUBCUTANEOUS SOLUTION  
RECONSTITUTED 4 MG, 5 MG, 6 MG

| PA Criteria                  | Criteria Details                                     |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescribed by HIV specialist                         |
| Coverage Duration            | 48 weeks   |
| Other Criteria               | Diagnosis of wasting or cachexia associated with HIV |
| Indications                  | All Medically-accepted Indications.                  |
| Off Label Uses               |  |

# SIGNIFOR

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## Products Affected

- SIGNIFOR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             | Deny if less than 18 years   |
| Prescriber Restrictions      | Prescribed by an endocrinologist   |
| Coverage Duration            | Remainder of contract year   |
| Other Criteria               | Documentation of BOTH of the following: (1) diagnosis of (pituitary) Cushing's disease AND (2) pituitary surgery is not an option or has not been curative |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# SILDENAFIL

## Products Affected

- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Documentation of concomitant nitrate use   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Deny if not prescribed by Cardiologist or Pulmonologist  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (1) Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV and BOTH of the following (a) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography, (b) Mean pulmonary artery pressure greater than or equal 25 mm Hg at rest or greater than 30 mm Hg with exertion. (2) diagnosis of secondary Raynaud's phenomenon and inadequate response or inability to tolerate a calcium channel blocker |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# SILENOR

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## Products Affected

- *doxepin hcl oral tablet*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | Remainder of contract year  |
| Other Criteria               | Documentation of insomnia with inadequate response or inability to tolerate ramelteon (Rozerem) |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# SILIQ

## Products Affected

- SILIQ

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of live vaccines prior to the start of therapy.   |
| <b>Age Restrictions</b>             | Deny if less than 18 years  |
| <b>Prescriber Restrictions</b>      | Prescribed by a dermatologist   |
| <b>Coverage Duration</b>            | Initial: 16 weeks Reauthorization: 1 year   |
| <b>Other Criteria</b>               | Documentation of ALL of the following: 1) plaque psoriasis and 2) inadequate response or inability to tolerate both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate 3) member has been evaluated for depression and suicidal ideations using the PHQ-9 Reauthorization criteria BOTH of the following: 1) member has positive response to therapy 2) member has been evaluated for depression and suicidal ideations using the PHQ-9 |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# SIMPONI

## Products Affected

- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to start of therapy.   |
| <b>Age Restrictions</b>             | Deny if less than 18 years  |
| <b>Prescriber Restrictions</b>      | RA, AS: Prescribed by a rheumatologist. PsA: Prescribed by a rheumatologist or dermatologist. UC: Prescribed by a gastroenterologist.   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Ankylosing Spondylitis: inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate. Psoriatic Arthritis: Inadequate response or inability to tolerate to TWO of the following: (a) Humira, (b) Enbrel, (c) Xeljanz/Xeljanz XR OR documentation demonstrating that a trial may be inappropriate. Rheumatoid arthritis: BOTH of the following (1) Inadequate response or inability to tolerate to TWO of the following: (a) Humira, (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR OR documentation demonstrating that a trial may be inappropriate AND (2) concurrent therapy with methotrexate. Ulcerative Colitis: inadequate response or inability to tolerate adalimumab (Humira) or documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# SIRTURO

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## Products Affected

- SIRTURO

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Sirturo (bedaquiline) will be administered by directly observed therapy (DOT).  |
| <b>Age Restrictions</b>             | Patient is 5 years of age or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by infectious disease specialist or pulmonologist  |
| <b>Coverage Duration</b>            | 24 weeks  |
| <b>Other Criteria</b>               | Documentation of ONE of the following: (1) medication will be used in combination with at least 3 other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro OR (2) If in vitro testing results are unavailable, treatment will be initiated in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# SKYRIZI

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## Products Affected

- SKYRIZI (150 MG DOSE)

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to the start of therapy |
| <b>Age Restrictions</b>             | Deny if less than 18 years of age  |
| <b>Prescriber Restrictions</b>      | Prescribed by a dermatologist  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# STELARA

## Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB)  |
| <b>Age Restrictions</b>             | (PsO): Member is 6 years of age or older. (PsA, Crohn's Disease, UC): Member is 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | Crohn's or Ulcerative Colitis (UC): prescribed by Gastroenterologist. Plaque psoriasis: prescribed by Dermatologist. Psoriatic Arthritis: prescribed by Dermatologist or Rheumatologist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | Subject to Part B vs Part D review. Part D is medically necessary when there is ONE of the following (1) psoriasis (PsO) and ONE of the following (a) member 6 to 17 years of age: an inadequate response or inability to tolerate etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate (b) member 18 years of age and older: inadequate response or inability to tolerate BOTH of the following: (a) ONE of the following: (i) Humira, (ii) Enbrel, or (iii) Skyrizi AND (b) Cosentyx OR documentation demonstrating that a trial may be inappropriate OR (2) psoriatic arthritis (PsA) and an inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate OR (3) Crohn's Disease: documentation of inadequate response or inability to tolerate adalimumab (Humira) or documentation demonstrating that a trial may be inappropriate OR (4) Ulcerative Colitis (UC): documentation of inadequate response or inability to tolerate adlimumab (Humira) or documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# SYMDEKO

## Products Affected

- SYMDEKO ORAL TABLET THERAPY PACK 100-150 & 150 MG, 50-75 & 75 MG

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | If the patient's genotype is unknown, an FDA-cleared test must be used to detect the presence of CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test                                 |
| <b>Age Restrictions</b>             | Patient is 6 years of age or older   |
| <b>Prescriber Restrictions</b>      | Prescribed by pulmonologist  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ALL of the following (1) Diagnosis of Cystic Fibrosis, (2) One of the following: a) Member is homozygous for the F508del mutation, or b) Member has at least one tezacaftor/ivacaftor responsive mutation in the CFTR gene. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# SYMLIN

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## Products Affected

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION  
PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION  
PEN-INJECTOR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Gastroparesis.   |
| Required Medical Information |  |
| Age Restrictions             | 18 years of age or older   |
| Prescriber Restrictions      |  |
| Coverage Duration            | Indefinite   |
| Other Criteria               | Documentation of diagnosis of diabetes (Type 1 or Type 2) and both of the following: (1) inadequate response to optimal insulin monotherapy and (2) concurrent use of mealtime insulin |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# TAFAMIDIS

## Products Affected

- VYNDAMAX
- VYNDAQEL

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if less than 18 years of age  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a cardiologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | <p>BOTH of the following are met: 1) Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) confirmed by one of the following: a) patient has a transthyretin (TTR) mutation (e.g., V122I), b) cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, or c) all of the following: echocardiogram or cardiac magnetic resonance image suggestive of amyloidosis, scintigraphy scan suggestive of cardiac TTR amyloidosis, and absence of light-chain amyloidosis, 2) One of the following: a) History of heart failure (HF), with at least one prior hospitalization for HF, or b) presence of clinical signs and symptoms of HF (e.g., dyspnea, edema), c) Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure,</p> <p>REAUTHORIZATION CRITERIA: 1) Documentation of positive clinical response to therapy, 2) Patient continues to have NYHA Functional Class I, II, or III heart failure, 3) Prescribed by or in consultation with a cardiologist.</p> |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# TAKHZYRO

## Products Affected

- TAKHZYRO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Deny if not prescribed by an allergist or immunologist  |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Subject to Part B vs Part D review and if part D is medically necessary when ALL of the following criteria are met: (1) Diagnosis of hereditary angioedema (HAE) (2) history of laryngeal edema or airway compromise with an episode of HAE or a history of at least 2 HAE attacks per month, AND (3) inadequate response or inability to tolerate 17 alpha-alkylated androgens (e.g. danazol, oxandrolone, stanozolol) or anti-fibrinolytic agents (e.g. epsilon aminocaproic acid, tranexamic acid) for HAE prophylaxis |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# TALTZ

## Products Affected

- TALTZ

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of Herpes Zoster vaccine prior to the start of therapy.  |
| <b>Age Restrictions</b>             | (PsO): Member is 6 years of age or older. (PsA, AS, nr-axSpA): Member is 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | Plaque Psoriasis: Prescribed by a dermatologist. PsA: Prescribed by a dermatologist or rheumatologist. AS and nr-axSpA: Prescribed by a rheumatologist.  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | ONE the following: (1) Non-radiographic axial Spondyloarthritis (nr-axSpA) AND inadequate response or inability to tolerate two NSAIDs OR Cosentyx OR documentation demonstrating that a trial may be inappropriate, OR (2) ankylosing spondylitis (AS), or psoriatic arthritis (PsA) and inadequate response or inability to tolerate Cosentyx or documentation demonstrating that a trial may be inappropriate, OR (3) Plaque psoriasis (PsO) and ONE of the following: (A) For members 6 to 17 years of age: an inadequate response or inability to tolerate Enbrel or documentation demonstrating that a trial may be inappropriate, OR (B) For members 18 years of age or older: an inadequate response or inability to tolerate Cosentyx or documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# TAVALISSE

## Products Affected

- TAVALISSE

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Documentation of baseline platelet count less than 30,000/mcL  |
| <b>Age Restrictions</b>             | Deny if less than 18 years of age  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with hematologist/oncologist  |
| <b>Coverage Duration</b>            | Initial and Continuation criteria is 12 months   |
| <b>Other Criteria</b>               | Approved when there is documentation of an inadequate response or inability to tolerate ONE of the following: 1) Corticosteroids, 2) Immunoglobulins, 3) Splenectomy, 4) Thrombopoietin receptor agonists (e.g., Nplate, Promacta), or 5) rituximab (Rituxan). Continuation criteria: Fostamatinib (Tavalisse) is re-approved when there is documentation of a positive clinical response to Tavalisse therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# TEGSEDI

## Products Affected

- TEGSEDI

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Documented presence of cardiac or renal manifestations, or motor, sensory, or autonomic neuropathy related to the hATTR amyloidosis with polyneuropathy (e.g., neuropathic pain, muscle weakness that affects daily living, orthostatic hypotension, diarrhea, nausea, vomiting, heart failure, arrhythmias, proteinuria, renal failure, vision disorders, such as vitreous opacity, dry eyes, glaucoma, or pupils with an irregular or scalloped appearance)   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist   |
| <b>Coverage Duration</b>            | 16 months for initial and indefinite for continuation   |
| <b>Other Criteria</b>               | Documentation is provided of BOTH of the following are met: (1) Diagnosis of hATTR amyloidosis with polyneuropathy confirmed by molecular genetic testing that reveals pathogenic variation(s) in the TTR gene (e.g. variation of V30M), AND (2) Documentation of ONE of the following baseline ambulation parameters in either the Familial Amyloid Polyneuropathy (FAP) Stage or Polyneuropathy Disability (PND) Score (a) Stage 1 (unimpaired ambulation) or 2 (assisted ambulation) on the Familial Amyloid Polyneuropathy (FAP) staging tool, or (b) Score I, II, IIIa, or IIIb on the Polyneuropathy Disability (PND) scoring tool. CONTINUATION CRITERIA: (1) Documented improvement or stability in the signs and symptoms hATTR amyloidosis with polyneuropathy (e.g., neuropathic pain, muscle weakness that affects daily living, orthostatic hypotension, diarrhea, nausea, vomiting, heart failure, arrhythmias, proteinuria, renal failure, vision disorders, such as vitreous opacity, dry eyes, glaucoma, or pupils with an irregular or scalloped appearance), based on objective or standard evaluation scales, and (2) ONE of the following: (a) Stage 1 (unimpaired ambulation) or 2 (assisted ambulation) on the Familial Amyloid Polyneuropathy (FAP) staging tool, or (b) Score I, II, IIIa, or IIIb on the Polyneuropathy Disability (PND) scoring tool |

| PA Criteria           | Criteria Details                    |
|-----------------------|-------------------------------------|
| <b>Indications</b>    | All Medically-accepted Indications. |
| <b>Off Label Uses</b> |                                     |

# TESTOSTERONE PRODUCTS

## Products Affected

- *testosterone cypionate intramuscular solution* 100 mg/ml, 200 mg/ml
- *testosterone enanthate intramuscular solution*
- *testosterone transdermal gel* 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)
- *testosterone transdermal solution*
- XYOSTED

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Treatment of Sexual or Erectile Dysfunction  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | For Delayed Puberty: Diagnosis of delayed puberty in male patients (Applies to Testosterone Enanthate only). For Breast Cancer: Diagnosis of inoperable breast cancer in female patients (Applies to Testosterone Enanthate only). For Hypogonadism: (New starts only): Attestation that diagnosis was initially confirmed by ALL of the following: (1) Two early morning total testosterone levels below 300 ng/dL measured on separate occasions, (2) Normal Prolactin Level, and (3) physical or cognitive symptoms of testosterone deficiency (e.g. physical: fatigue, sleep disturbances, decreased activity, cognitive: depressive symptoms, cognitive dysfunction, loss of concentration, poor memory, irritability) and ONE of the following (1) negative history of prostate and breast cancer OR (2) Both of the following (a) history of prostate cancer with stable PSA less than or equal to 4ng/dL for 2 years and (b) documentation that the risk versus benefit has been assessed. (Continuation of testosterone therapy for hypogonadism): ONE of the following (1) negative history of prostate and breast cancer OR (2) Both of the following (a) history of prostate cancer with stable PSA less than or equal to 4ng/dL for 2 years and (b) documentation that the risk versus benefit has been assessed. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# TOPICAL RETINOID PRODUCTS

## Products Affected

- *adapalene external cream*
- *adapalene external gel*
- *adapalene external pad*
- *adapalene-benzoyl peroxide*
- AVITA
- *clindamycin-tretinoin*
- EPIDUO FORTE
- *tretinoin external*

| PA Criteria                         | Criteria Details                    |
|-------------------------------------|-------------------------------------|
| <b>Exclusion Criteria</b>           | Cosmetic use                        |
| <b>Required Medical Information</b> |                                     |
| <b>Age Restrictions</b>             |                                     |
| <b>Prescriber Restrictions</b>      |                                     |
| <b>Coverage Duration</b>            | Remainder of contract year          |
| <b>Other Criteria</b>               |                                     |
| <b>Indications</b>                  | All Medically-accepted Indications. |
| <b>Off Label Uses</b>               |                                     |

# TREMFYA

## Products Affected

- TREMFYA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists   |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB). For new starts only: at least 2 weeks passed since administration of live vaccines prior to the start of therapy.  |
| <b>Age Restrictions</b>             | Deny if less than 18 years   |
| <b>Prescriber Restrictions</b>      | (PsO): Prescribed by a dermatologist. (PsA): Prescribed by a dermatologist or rheumatologist.  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of ONE the following: (1) plaque psoriasis (PsO) and inadequate response or inability to tolerate Cosentyx or documentation demonstrating that a trial may be inappropriate, OR (2) psoriatic arthritis (PsA) and an inadequate response or inability to tolerate Cosentyx or documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# TRIKAFTA

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## Products Affected

- TRIKAFTA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> | Member has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a FDA-cleared cystic fibrosis mutation test |
| <b>Age Restrictions</b>             | Patient is 12 years of age or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by a pulmonologist  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               |  |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# UPTRAVI

## Products Affected

- UPTRAVI

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Not taken in combination with a prostanoid/prostacyclin analogue (e.g. epoprostenol, iloprost, treprostinil)   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      | Prescribed by Cardiologist or Pulmonologist  |
| <b>Coverage Duration</b>            | 6 month for initial authorization and 12 months for re-authorizations  |
| <b>Other Criteria</b>               | Approved when ALL of the following inclusion criteria are met: (1) Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV AND (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography AND (3) Documentation of mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion AND (4) inadequate response or inability to tolerate TWO of the following (a) an endothelin receptor antagonist (Tracleer if naive to the class) (b) a phosphodiesterase inhibitor (sildenafil if naive to the class) (c) riociguat (Adempas). RE-AUTHORIZATION CRITERIA: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# VALCHLOR

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## Products Affected

- VALCHLOR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescribed by an Oncologist or Dermatologist   |
| Coverage Duration            | 12 months  |
| Other Criteria               | Documentation of a diagnosis of Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# VECAMEYL

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## Products Affected

- VECAMEYL

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Uremia, glaucoma, organic pyloric stenosis, coronary insufficiency, recent myocardial infarction   |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             |  |
| <b>Prescriber Restrictions</b>      |  |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Documentation of BOTH of the following: (1) diagnosis of moderately severe to severe essential hypertension or malignant hypertension AND (2) an inadequate response or inability to tolerate at least two antihypertensive medications in different classes |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# WAKIX

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## Products Affected

- WAKIX

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> | Narcolepsy: Diagnosis of narcolepsy. Both of the following: (1) Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT), (2) Inadequate response or inability to tolerate modafinil or armodafinil |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by a neurologist or sleep specialist   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               |   |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# XELJANZ

## Products Affected

- XELJANZ
- XELJANZ XR

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists or potent immunosuppressants such as azathioprine or cyclosporine  |
| <b>Required Medical Information</b> | Documentation for evaluation of active or latent Tuberculosis (TB)  |
| <b>Age Restrictions</b>             | Deny if less than 18 years  |
| <b>Prescriber Restrictions</b>      | RA: Prescribed by a rheumatologist. PsA: Prescribed by a dermatologist or rheumatologist. UC: Prescribed by a gastroenterologist.   |
| <b>Coverage Duration</b>            | Indefinite  |
| <b>Other Criteria</b>               | ONE of the following: (1) RHEUMATOID ARTHRITIS, (2) For PSORIATIC ARTHRITIS: Documentation of ONE of the following: (1) inadequate response or inability to tolerate adalimumab (Humira) OR etanercept (Enbrel) or (2) documentation demonstrating that a trial may be inappropriate. (3) For Ulcerative Colitis: documentation of inadequate response or inability to tolerate adalimumab (Humira) or documentation demonstrating that a trial may be inappropriate. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# XENAZINE/AUSTEDO

## Products Affected

- AUSTEDO
- *tetrabenazine*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           |   |
| <b>Required Medical Information</b> |   |
| <b>Age Restrictions</b>             |   |
| <b>Prescriber Restrictions</b>      | Prescribed by a neurologist or a psychiatrist   |
| <b>Coverage Duration</b>            | 3 month initial auth for TD, indefinite for TD & Tourette's re-auth & Chorea-Huntington's disease   |
| <b>Other Criteria</b>               | For diagnosis of Tardive dyskinesia (TD) documentation is provided of ONE of the following: (a) Persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering or discontinuation of the offending medication, or (b) Member is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. For diagnosis of Tourette's syndrome: Patient has tics associated with Tourette's syndrome, AND inadequate response or inability to tolerate haloperidol or risperidone. Continuation of therapy: Documentation of positive clinical response to therapy. |
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off Label Uses</b>               |   |

# XGEVA

## Products Affected

- XGEVA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      | Prescribed by oncologist or hematologist  |
| Coverage Duration            | Indefinite  |
| Other Criteria               | Subject to Part B vs Part D review. Part D is medically necessary when there is documentation of ONE of the following diagnoses: (1) prevention of skeletal related events in multiple myeloma or bone metastases from solid tumors OR (2) Giant cell tumor of the bone (in adults and skeletally mature adolescents) that is unresectable or where surgical resection is likely to result in severe morbidity OR (3) hypercalcemia of malignancy refractory to bisphosphonates |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# XIFAXAN

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## Products Affected

- XIFAXAN ORAL TABLET 550 MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | For Hepatic Ecephalopathy: Indefinite FOR IBS: 2 weeks  |
| Other Criteria               | INITIAL AUTHORIZATION: ONE of the following: (A) Diagnosis of hepatic disease with risk for hepatic encephalopathy (ie previous episode of hepatic encephalopathy, advanced liver disease, hepatocellular carcinoma) AND inadequate response or inability to tolerate lactulose OR (B) Diagnosis of irritable bowels syndrome- diarrhea AND inadequate response or inability to tolerate BOTH of the following: (1) ONE of the following: (1) ONE Tricyclic antidepressant or (2)selective serotonin reuptake inhibitor and (2) dicyclomine. REAUTHORIZATION CRITERIA FOR IBS: BOTH of the following: (1) Member does not exceed 3 courses (42 days) of therapy AND (2) No documentation of rifaximin (Xifaxin) treatment within the last 10 weeks. |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# XOLAIR

## Products Affected

- XOLAIR

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           |  |
| <b>Required Medical Information</b> |  |
| <b>Age Restrictions</b>             | Deny if patient is less than 6 years   |
| <b>Prescriber Restrictions</b>      | Prescribed by Allergist, Dermatologist, Immunologist, or Pulmonologist   |
| <b>Coverage Duration</b>            | Indefinite   |
| <b>Other Criteria</b>               | Subject to Part B vs Part D review. Part D is medically necessary FOR DIAGNOSIS OF MODERATE TO SEVERE PERSISTENT ALLERGIC ASTHMA: Documentation of ALL of the following: (1) The individual has a positive skin test or in vitro reactivity to a perennial aeroallergen, (2) The individual has a baseline serum IgE level of between 30 IU/mL and 1300 IU/mL AND (3) Inadequate response or inability to tolerate a combination of high-dose inhaled corticosteroids (ICS) with a long-acting beta-agonist (LABA). FOR DIAGNOSIS OF CHRONIC URTICARIA: Documentation of an inadequate response, contraindication or inability to tolerate ONE second-generation H1 antihistamine at the maximally tolerated dose in addition to ANY of the following: (a) leukotriene receptor antagonist (e.g.. montelukast) (b) histamine H2-receptor antagonist (e.g. ranitidine, cimetidine, famotidine), (c) substituting to a different second-generation antihistamine, (d) systemic glucocorticosteroids or (e) cyclosporine, AND will be used concurrently with an h1 antihistamine, unless there is contraindication or intolerance to H1 antihistamines. |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# XYREM

## Products Affected

- XYREM

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           |  |
| Required Medical Information |  |
| Age Restrictions             |  |
| Prescriber Restrictions      | Prescribed by a neurologist or sleep specialist  |
| Coverage Duration            | 12 months (initial and reauthorization)  |
| Other Criteria               | Documentation of 1) cataplexy in narcolepsy OR 2) excessive daytime sleepiness in narcolepsy with inadequate response or inability to modafinil.<br>REAUTHORIZATION CRITERIA: Documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale) AND re-evaluated every 3 months |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# ZAVESCA

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## Products Affected

- *miglustat*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             | Deny if less than 18 years  |
| Prescriber Restrictions      |   |
| Coverage Duration            | Remainder of contract year  |
| Other Criteria               | Documentation of mild to moderate type 1 Gaucher disease AND enzyme replacement therapy is not a therapeutic option (e.g. because of allergy, hypersensitivity, or poor venous access). |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

# ZORBTIVE

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## Products Affected

- ZORBTIVE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           |   |
| Required Medical Information |   |
| Age Restrictions             |   |
| Prescriber Restrictions      |   |
| Coverage Duration            | 6 weeks   |
| Other Criteria               | Used in conjunction with optimal management for short bowel syndrome, including specialized nutrition support |
| Indications                  | All Medically-accepted Indications.   |
| Off Label Uses               |   |

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| <i>testosterone enanthate intramuscular solution</i> .....   | 145 | XELJANZ .....                     | 153   |
| <i>testosterone transdermal gel 10 mg/act (2%),<br/>12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%),<br/>20.25 mg/act (1.62%), 25 mg/2.5gm (1%),<br/>40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)</i> ..... | 145 | XELJANZ XR .....                  | 153   |
| <i>testosterone transdermal solution</i> .....   | 145 | XENLETA ORAL .....                | 99    |
| <i>tetrabenazine</i> .....   | 154 | XGEVA .....                       | 155   |
| THALOMID .....   | 100 | XIFAXAN ORAL TABLET 550 MG .....  | 156   |
| TIBSOVO .....  | 100 | XOLAIR .....                      | 157   |
| TOBI PODHALER .....  | 69  | XOSPATA .....                     | 100   |
| <i>tolvaptan oral tablet 30 mg</i> .....   | 127 | XPOVIO (100 MG ONCE WEEKLY) ..... | 100   |
| TRACLEER .....   | 102 | XPOVIO (40 MG ONCE WEEKLY) .....  | 100   |
| TRELSTAR MIXJECT .....   | 89  | XPOVIO (40 MG TWICE WEEKLY) ..... | 100   |
| TREMFYA .....  | 147 | XPOVIO (60 MG ONCE WEEKLY) .....  | 100   |
| <i>tretinoin external</i> .....  | 146 | XPOVIO (60 MG TWICE WEEKLY) ..... | 100   |
| TRIKAFTA .....   | 148 | XPOVIO (80 MG ONCE WEEKLY) .....  | 100   |
|  |     | XPOVIO (80 MG TWICE WEEKLY) ..... | 100   |
|  |     | XTAMPZA ER .....                  | 4, 56 |
|  |     | XTANDI .....                      | 100   |
|  |     | XYOSTED .....                     | 145   |
|  |     | XYREM .....                       | 158   |
|  |     | YONSA .....                       | 100   |
|  |     | ZEJULA .....                      | 100   |
|  |     | ZELBORAF .....                    | 100   |
|  |     | ZEMAIRA .....                     | 124   |
|  |     | ZEMDRI .....                      | 88    |

|  |     |
|--|-----|
| ZEPATIER .....   | 90  |
| ZOLINZA .....  | 100 |
| <i>zolpidem tartrate er oral tablet extended<br/>release 12.5 mg</i> ..... | 62  |
| <i>zolpidem tartrate oral tablet 10 mg</i> .....                           | 62  |
| ZOMACTON .....   | 52  |
| ZORBTIVE .....   | 160 |
| ZYDELIG .....  | 100 |
| ZYKADIA ORAL TABLET .....  | 100 |
| ZYTIGA .....   | 100 |