



Keystone 65 HMO

**Keystone 65 Basic HMO**  
**Keystone 65 Focus Rx HMO**  
**2018 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 11/1/18. For more recent information or other questions, please contact our Member Help Team at 1-800-645-3965 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 February 15 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 Basic Rx and Keystone 65 Focus 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, 2019, and from time to time during the year.

Keystone 65 offers HMO plans with a Medicare contract. Enrollment in Keystone 65 Medicare Advantage plans depends on contract renewal.

Benefits underwritten by Keystone Health Plan East, 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 *2018 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 Basic Rx and Keystone 65 Focus 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 *2018 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 Basic Rx and Keystone 65 Focus 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 159. 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 at 1-800-645-3965.

# ABUSE DETERRENT OPIOID

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## Products Affected

- XTAMPZA ER

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
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

# ACTEMRA IV

## Products Affected

- ACTEMRA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent therapy with other biological disease-modifying anti-rheumatic drugs (DMARDs)
<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 18 years for diagnosis of RA or less than 2 years of age for diagnoses of sJIA and pJIA
<b>Prescriber Restrictions</b>	Deny if not prescribed by a Rheumatologist
<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 there is documentation of ONE of the following: (1) systemic juvenile idiopathic arthritis OR (2) polyarticular juvenile idiopathic arthritis or rheumatoid arthritis with an inadequate response to at least one disease-modifying antirheumatic drug (DMARDs) such as methotrexate

# ACTEMRA SQ

## Products Affected

- ACTEMRA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 18 years
<b>Prescriber Restrictions</b>	Deny if not prescribed by a Rheumatologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	For Polyarticular Juvenile rheumatoid arthritis, Systemic onset Juvenile chronic arthritis, and moderate to severe rheumatoid arthritis: documentation of inadequate response or inability to tolerate BOTH adalimumab (Humira) and etanercept (Enbrel) OR documentation demonstrating that a trial may be inappropriate. For Giant Cell Arteritis: documentation of inadequate response/inability to tolerate oral corticosteroids

# ACTHAR HP

## Products Affected

- HP ACTHAR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	2 years of age or younger for diagnosis of IS, 18 years of age or older for other indications
<b>Prescriber Restrictions</b>	Infantile spasms: pediatric neurologist or neonatologist, all other indications: neurologist, rheumatologist, nephrologist, pulmonologist, or ophthalmologist
<b>Coverage Duration</b>	Infantile Spasms=1 yr All Other=1 month

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Subject to Part B vs Part D review and if part D is medically necessary when ONE of the following is present: infantile spasms OR there has been inadequate response or inability to tolerate systemic steroids (eg prednisone, methylprednisolone) and ONE of the following (1) acute exacerbation of multiple sclerosis currently receiving maintenance treatment for MS (eg 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</p>

# ACUTE HAE AGENTS

## Products Affected

- BERINERT
- FIRAZYR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by an allergist or immunologist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Subject to Part B vs Part D review and if 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)

# ADEMPAS

## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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. Reauthorization criteria: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist.

# ALDURAZYME

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## Products Affected

- ALDURAZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if part D is medically necessary when there is documentation of Mucopolysaccharidosis, Type I (Hurler and Hurler-Scheie forms) and Scheie form with moderate to severe symptoms.

# ALGLUCOSIDASE ALFA

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## Products Affected

- LUMIZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if part D is medically necessary in individuals with diagnosis of Pompe disease (GAA deficiency)

# AMPYRA

## Products Affected

- AMPYRA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# ANADROL

## Products Affected

- ANADROL-50

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	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

# ANDROGEL

## Products Affected

- ANDROGEL PUMP TRANSDERMAL GEL (1.62%)  
20.25 MG/ACT (1.62%)
- ANDROGEL TRANSDERMAL GEL 20.25  
MG/1.25GM (1.62%), 40.5 MG/2.5GM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Normal prolactin level, low (morning) testosterone level [For new starts only]
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Remainder of contract year
<b>Other Criteria</b>	Documentation of ONE of the following (1) negative history of prostate and breast cancer OR (2) history of prostate cancer status post prostatectomy and documentation that the risk versus benefit has been assessed

# BENLYSTA

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## Products Affected

- BENLYSTA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if 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, immunosuppressives, nonsteroidal anti-inflammatory drugs (NSAIDS)

# BOTOX

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## Products Affected

- BOTOX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Subject to Part B vs Part D review and if part D is medically necessary when there is documentation of ONE of the following diagnoses: (1) Severe primary focal hyperhidrosis (2) Blepharospasms associated with dystonia, (3) Cervical dystonia (4) adult patients with chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer) and BOTH of the following (a) an inadequate response or inability to tolerate at least 2 agents from different classes (e.g., Tricyclic antidepressants (TCAs), SNRIs or SSRIs, Anticonvulsants, Beta blockers, Calcium channel blockers) AND (b) prescribed by a neurologist (5) Overactive bladder/ Urinary incontinence with inadequate response or an inability to tolerate an anticholinergic medication (6) Strabismus AND at least one of the following: (a) diplopia, (b) abnormal head turn, (c) asthenopia, (d) impairment of peripheral vision due to esotropia (7) spasticity of limbs related to any of the following: (a) cerebral palsy, (b) demyelinating disease of CNS, (c) brain injury, (d) hemiplegia or paraplegia, (e) multiple sclerosis, (f) spinal cord injury (8) Sialorrhea (excessive drooling) due to disabling conditions such as motor neuron disease or Parkinson's disease with an inadequate response or inability to tolerate glycopyrrolate or transdermal scopolamine (9) Chronic anal fissure or anal spasm that has been unresponsive to conventional treatments (e.g steroids, nitroglycerin) (10) Focal dystonia or Spastic dystonia (11) Spasmodic dystonia or Laryngeal dystonia</p>

# CARBAGLU

## Products Affected

- CARBAGLU

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
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)

# CAYSTON

## Products Affected

- CAYSTON

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 7 years
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Remainder of contract year
<b>Other Criteria</b>	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

# CERDELGA

## Products Affected

- CERDELGA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# CESAMET/SANCUSO

## Products Affected

- CESAMET
- SANCUSO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	Documentation of chemotherapy induced nausea and vomiting AND inadequate response to or inability to tolerate (a) ondansetron or granisetron and (b) aprepitant

# CGRP ANTAGONISTS

## Products Affected

- AIMOVIG 140 DOSE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 neurologist or headache specialist specialist certified by the United Council for Neurologic Subspecialties
<b>Coverage Duration</b>	6 months for initial authorization, 12 months for reauthorization
<b>Other Criteria</b>	<p>Approved when ONE of the following inclusion criteria are met: (1) Diagnosis of episodic migraines defined as 4 to14 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 ONE of the following (a) 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 OR (b) Inadequate response or inability to tolerate onabotulinumtoxin A (Botox) 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)</p>

# CHOLBAM

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 disorder
<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.

# CIMZIA

## Products Affected

- CIMZIA PREFILLED
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not prescribed by a Gastroenterologist or Rheumatologist.
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Documentation of ONE of the following: (1) for diagnosis of Ankylosing Spondylitis, Psoriatic Arthritis or Rheumatoid Arthritis: inadequate response or inability to tolerate both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate (2) for diagnosis of Crohn's Disease: inadequate response or inability to tolerate adalimumab (Humira)

# CINRYZE

## Products Affected

- CINRYZE
- HAEGARDA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by an allergist or immunologist
<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 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

# CORLANOR

## Products Affected

- CORLANOR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	(1) stable, symptomatic chronic heart failure (2) left ventricular ejection fraction less than or equal to 35% and (3) sinus rhythm with resting heart rate greater than or equal to 70 beats per minute
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Patient is clinically stable for at least 4 weeks on an optimized and stable clinical 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

# COSENTYX

## Products Affected

- COSENTYX 300 DOSE
- COSENTYX SENSOREADY 300 DOSE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not prescribed by a Rheumatologist or dermatologist.
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Diagnosis of plaque psoriasis, psoriatic arthritis, or ankylosing spondylitis and inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate

# CRESEMBA [ORAL]

## Products Affected

- CRESEMBA ORAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 18 years
<b>Prescriber Restrictions</b>	prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	Remainder of contract year
<b>Other Criteria</b>	Documentation of either of the following (1) for use in the treatment of invasive aspergillosis after inadequate response or inability to tolerate Voriconazole (Vfend) OR for a diagnosis of mucormycosis

# CYSTARAN

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## Products Affected

- CYSTARAN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Documentation of BOTH of the following: (1) diagnosis of cystinosis AND (2) patient has corneal cystine crystal accumulation

# DEFERASIROX

## Products Affected

- EXJADE
- JADENU
- JADENU SPRINKLE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if than 2 years
<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. 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

# DICLOFENAC 3% PRODUCTS

## Products Affected

- *diclofenac sodium transdermal gel 3 %*

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Deny if less than 18 years
Prescriber Restrictions	
Coverage Duration	90 days
Other Criteria	Documentation of diagnosis of Actinic Keratoses

# DIFICID

## Products Affected

- DIFICID

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 18 years
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	10 days
<b>Other Criteria</b>	Documentation of the presence of Clostridium difficile-associated diarrhea confirmed by laboratory testing AND documentation of inadequate response or inability to tolerate metronidazole OR vancomycin RE-AUTHORIZATION CRITERIA: documentaton of consultation with an infectious disease specialist

# DOPTELET

## Products Affected

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Documentation of baseline platelet count less than 50,000/mcL
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	

# DUPIXENT

## Products Affected

- DUPIXENT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 18 years old
<b>Prescriber Restrictions</b>	Deny if prescriber is not a dermatologist, allergist, immunologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	BOTH of the following: (1) diagnosis or 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

# DYSPO

## Products Affected

- DYSPO INTRAMUSCULAR SOLUTION  
RECONSTITUTED 500 UNIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review

# ELAPRASE

## Products Affected

- ELAPRASE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if age is less than 16 months
<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 for the diagnosis of Hunter Syndrome (mucopolysaccharidosis type II [MPS II])

# EMFLAZA

## Products Affected

- EMFLAZA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 5 years of age
<b>Prescriber Restrictions</b>	Deny if not prescribed by a neurologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Inadequate response or inability to tolerate prednisone

# EMSAM

## Products Affected

- EMSAM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# ENBREL

## Products Affected

- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not prescribed by Rheumatologist or 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, Ankylosing Spondylitis, Psoriatic Arthritis or Juvenile Idiopathic Arthritis: 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.

# ENDARI

## Products Affected

- ENDARI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by a hematologist or oncologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Member has had 2 or more painful sickle cell crises within the past 12 months

# EPCLUSA

## Products Affected

- EPCLUSA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	HCV GT
<b>Age Restrictions</b>	Deny if less than 18 years
<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

# EUCRISA

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## Products Affected

- EUCRISA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 2 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Documentation of BOTH of the following: (1) Inadequate response to non-pharmacological interventions (i.e. use of moisturizers), (2) Inadequate response or inability to tolerate at least one of the following: (a) generic topical tacrolimus, (b) generic, prescription medium potency or higher topical steroid.

# EXONDYS

## Products Affected

- EXONDYS 51

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	patient has a confirmed mutation of the DMD gene that is amenable to exon 51 skipping
<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

# FABRAZYME

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## Products Affected

- FABRAZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if part D is medically necessary when there is a documentation of Fabry disease.

# FENTANYL CITRATE LOZENGE

## Products Affected

- *fentanyl citrate buccal*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 16 years
<b>Prescriber Restrictions</b>	
<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

# FERRIPROX

## Products Affected

- FERRIPROX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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>	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

# FORTEO

## Products Affected

- FORTEO SUBCUTANEOUS SOLUTION  
600 MCG/2.4ML
- TYMLOS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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.)
<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>	Inadequate response or inability to tolerate at least one of the following (a) bisphosphonates, (b) hormone replacement therapy, (c) selective-estrogen receptor modulators (SERMs). Reauthorization criteria: documentation that cumulative lifetime therapy does not exceed 2 years

# GATTEX

## Products Affected

- GATTEX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Member left with less than 200 cm of functional small bowel
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Documentation of ALL of the following: (1) diagnosis of Short Bowel Syndrome AND (2) individual receives parenteral support at least three times per week. REAUTH CRITERIA: Reduction in parenteral support from baseline (prior to initiation of Gattex therapy)

# GAUCHER AGENTS

## Products Affected

- CERZYME INTRAVENOUS SOLUTION  
RECONSTITUTED 400 UNIT
- ELELYSO
- VPRIV

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if part D is medically necessary when BOTH of the following criteria are met: (1) diagnosis of Type 1 Gaucher's disease AND (2) presence of at least ONE of the following conditions: anemia, bone disease, hepatomegaly, splenomegaly or thrombocytopenia.

# GROWTH HORMONES

## Products Affected

- GENOTROPIN
- GENOTROPIN MINISQUICK
- HUMATROPE
- NORDITROPIN FLEXPPO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- SAIZEN
- SAIZENPREP
- ZOMACTON

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Recommendation by an endocrinologist or nephrologist
<b>Coverage Duration</b>	12 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	REAUTHORIZATION for additional 12 months: Annual clinical re-evaluation by the treating endocrinologist 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

# HARVONI

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## Products Affected

- HARVONI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hepatitis C Genotype
<b>Age Restrictions</b>	Deny if less than 12 years
<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

# HEPATITIS C AGENTS

## Products Affected

- DAKLINZA
- SOVALDI
- VIEKIRA PAK
- VIEKIRA XR
- VOSEVI
- ZEPATIER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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, Epclusa, or Mavyret where indicated.

# HETLIOZ

## Products Affected

- HETLIOZ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by a sleep specialist or neurologist
<b>Coverage Duration</b>	Remainder of contract year
<b>Other Criteria</b>	Diagnosis of a circadian period greater than 24 hours

# 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*
- *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, 40 mg, 60 mg, 80 mg*
- *oxycodone hcl oral tablet 30 mg*
- *oxymorphone hcl er oral tablet extended release 12 hour 20 mg, 30 mg, 40 mg*
- *oxymorphone hcl oral tablet 10 mg*
- *XTAMPZA ER*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 (b) member is tolerating medication appropriately AND (c) member has improved functioning AND (d) member is not being treated for substance abuse</p>

# HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AGENTS

## Products Affected

- JUXTAPID
- KYNAMRO SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Kynamro and Jutaxapid: 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>	
<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) Cutaneous or tendonous 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

# HRM

## Products Affected

- *benztropine mesylate oral*
- *butalbital-acetaminophen oral tablet 50-300 mg*
- *dicyclomine hcl intramuscular*
- *dicyclomine hcl oral*
- DIGITEK ORAL TABLET 250 MCG
- DIGOX ORAL TABLET 250 MCG
- *digoxin injection*
- *digoxin oral tablet 250 mcg*
- *dipyridamole oral*
- *ergoloid mesylates oral*
- *hydroxyzine hcl oral tablet*
- *methocarbamol injection solution 1000 mg/10ml*
- *methocarbamol oral*
- PHENADOZ RECTAL SUPPOSITORY 12.5 MG
- *promethazine hcl injection*
- *promethazine hcl oral syrup*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal*
- PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG
- *trihexyphenidyl hcl oral tablet*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# HRM ESTROGENS

## Products Affected

- AMABELZ
- *estradiol oral*
- *estradiol transdermal patch twice weekly*
- *estradiol-norethindrone acet*
- MIMVEY
- MIMVEY LO
- PREMARIN ORAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# HRM LONG ACTING SULFONYLUREAS

## Products Affected

- *glyburide micronized*
- *glyburide oral*
- *glyburide-metformin*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 glipizide and glimepiride OR (2) Documentation that the risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly

# HRM NON BENZODIAZEPINE HYPNOTICS

## Products Affected

- *eszopiclone*
- *zaleplon*
- *zolpidem tartrate*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 of ONE of the following: (1) Inadequate response or inability to tolerate ramelteon (Rozerem) OR (2) 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)

# HRM SHORT TERM SKELETAL MUSCLE RELAXANTS

## Products Affected

- *carisoprodol oral*
- *carisoprodol-aspirin*
- *cyclobenzaprine hcl oral*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 weeks
<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

# HRM TCAS

## Products Affected

- *amitriptyline hcl oral*
- *clomipramine hcl oral*
- *doxepin hcl oral*
- *imipramine hcl oral*
- *imipramine pamoate*
- *nortriptyline hcl oral*
- *perphenazine-amitriptyline*
- *trimipramine maleate oral*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 one generic SSRI (e.g. sertraline, fluoxetine, etc) or one generic SNRI (e.g. duloxetine, venlafaxine) OR (2) Documentation that the risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly

# HUMIRA

## Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 40 MG/0.8ML, 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 STARTER
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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, less than 6 years for Crohn's disease, less than 18 years for all other indications
<b>Prescriber Restrictions</b>	Deny if not 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

# ILARIS

## Products Affected

- ILARIS SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 2 years for SJIA, less than 4 years for other indications
<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 for ONE of the following diagnosis: (1) cryopyrin-associated periodic syndromes [CAPS], (2) systemic juvenile idiopathic arthritis, (3) Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), (4) Hyperimmunoglobulin D Syndrome (HIDS) /Mevalonate Kinase Deficiency (MKD) , (5) Familial Mediterranean Fever (FMF)

# INCRELEX

## Products Affected

- INCRELEX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Known or suspected malignancy, closed epiphyses
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 2 years
<b>Prescriber Restrictions</b>	
<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 REAUTHORIZATION: documentation of increase in growth velocity from baseline AND annual clinical re-evaluation by the treating endocrinologist

# INFLIXIMAB

## Products Affected

- INFLECTRA
- REMICADE
- RENFLEXIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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)
<b>Age Restrictions</b>	For Crohn's disease and Ulcerative Colitis: deny if less than 6 years, For Polyarticular Juvenile Idiopathic Arthritis (PJIA): deny if less than 4 year of age, For all other diagnosis: deny if less than 18 years of age.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Indefinite

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Subject to Part B vs Part D review and if part D is medically necessary for the diagnoses of: (1) active, moderate to severe ankylosing spondylitis and an inadequate response or inability to tolerate at least one other treatment such as NSAIDs, COX2 inhibitors, or methotrexate (2) moderate to severe ulcerative colitis or Crohn's disease and an inadequate response or inability to tolerate at least one conventional treatment e.g corticosteroids, aminosalicylates, immunomodulators (3) chronic, severe (i.e. extensive and/or disabling) plaque psoriasis for individuals who are candidates for systemic therapy and have had an inadequate response or are unable to tolerate other systemic therapies (4) Rheumatoid arthritis in combination with methotrexate or as monotherapy when the individual is intolerant of or has a contraindication to methotrexate and inadequate response to any DMARD (eg sulfasalazine, azathioprine, cyclophosphamide, cyclosporine, methotrexate, other anti-tumor necrosis factor agents) (5) active psoriatic arthritis and inability to tolerate or inadequate response to at least one DMARD (6) Wegener's granulomatosis with evidence of severe active disease and inadequate response or inability to tolerate corticosteroids and immunosuppressant agents (7) Chronic Pulmonary Sarcoidosis with a documentation of failure or intolerance to 3-month trial of corticosteroids and immunosuppressive agents (8) Ulcerative Colitis in Children who have moderate to severe active UC and who have had an inadequate response to conventional therapies (9) Pyoderma gangrenosum (10) Polyarticular juvenile idiopathic arthritis (JIA) with evidence of active disease and who have had a documented failure or intolerance to a 3-month trial of any of the FDA-approved biologic DMARD</p>

# INGREZZA

## Products Affected

- INGREZZA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a psychiatrist
<b>Coverage Duration</b>	Initial authorization: 3 months, Reauthorization: indefinite
<b>Other Criteria</b>	Diagnosis of moderate to severe tardive dyskinesia and (1) 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 to Ingrezza therapy

# INHALED TOBRAMYCIN

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## Products Affected

- TOBI PODHALER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	(1) diagnosis of cystic fibrosis AND (2) evidence of P. aeruginosa in the lungs

# INTRAVENOUS IMMUNE GLOBULIN (IVIG)

## Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 10 GM/100ML
- CARIMUNE NF INTRAVENOUS SOLUTION RECONSTITUTED 6 GM
- 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
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	primary immune deficiency disease(eg congenital hypogammaglobulinemia, immunodeficiency with increased IGM, common variable immunodeficiency Wiskott-Aldrich Syndrome, combined immunity deficiency)
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Subject to Part B vs Part D review and if 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 (ie steroids, immunosuppressants) OR (b) rapidly progressive disease in conjunction with conventional therapy (ie steroids, immunosuppressants) (2) Erythema multiforme major (SJS, TEN) and SCORTEN level 3 or greater (3) scleromyxedema (4) 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 (5) 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 (6) chronic B-cell lymphocytic leukemia with IgG less than 600mg/dL and recurrent, serious bacterial infections requiring antibiotic therapy (7) hematopoietic stem cell transplant and IgG less than 400mg/dL (8) 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 (9) solid organ transplant (10) chronic inflammatory demyelinating polyneuritis confirmed by electrodiagnostic testing or nerve biopsy and an inadequate response or inability to tolerate corticosteroids (11) 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 (12) Guillain Barre syndrome with impaired function (ie unable to stand or walk without aid) (13) Lambert Eaton myasthenic syndrome refractory to steroids, immunosuppressants, or cholinesterase inhibitors (14) multifocal motor neuropathy diagnosed by electrodiagnostic studies (15) acute exacerbations of MS unresponsive to steroids (16) myasthenia gravis refractory to at least 8 weeks of standard therapy (steroids, immunosuppressants, cholinesterase inhibitors) (17) myasthenic crisis (18) stiff person syndrome refractory to standard therapy (muscle relaxants, benzodiazepines, gabapentin) (19)</p>
	<p>severe, active SLE unresponsive to steroids (20) Kawasaki disease  CONTINUATION OF THERAPY CRITERIA: Documentation of clinical improvement using objective monitoring as appropriate to the diagnosis such as, but not limited to, Rankin score and Activities of Daily Living (ADL) scores.</p>

# JYNARQUE

## Products Affected

- JYNARQUE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Baseline serum transaminases and bilirubin prior to initiation of therapy
<b>Age Restrictions</b>	Deny if less than 18 years of age
<b>Prescriber Restrictions</b>	Deny if not prescribed by a nephrologist or kidney transplant specialist
<b>Coverage Duration</b>	3 months for initial and 12 months for re-authorization
<b>Other Criteria</b>	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

# KALYDECO

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## Products Affected

- KALYDECO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients with cystic fibrosis who are homozygous for the F508del mutation in the CFTR
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if age less than 2 years for granules and less than 6 years of age for tablets
<b>Prescriber Restrictions</b>	
<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.

# KANUMA

## Products Affected

- KANUMA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization: 3 month, Re-authorization: end of contract year
<b>Other Criteria</b>	Diagnosis of Lysosomal acid lipase (LAL) deficiency (also known as Wolman disease and cholesteryl ester storage disease [CESD]). Reauthorization criteria: Patient is responding to the medication as indicated by improvement in ALT/AST values, Serum lipid levels (LDL-C, non-HDL, TGs, HDL), hepatic fat content, organ volumes

# KEVEYIS

## Products Affected

- KEVEYIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomittant use of high dose Aspirin, severe pulmonary disease and hepatic insufficiency
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial criteria: 2 months Reauthorization: indefinite
<b>Other Criteria</b>	Reauthorization Criteria: Dichlorphenamide (Keveyis) is reapproved with documentation that prescriber has evaluated the patient's response to dichlorphenamide and recommends continuation of the treatment

# KEVZARA

## Products Affected

- KEVZARA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	Deny if not 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

# KINERET

## Products Affected

- KINERET SUBCUTANEOUS SOLUTION  
REFILLED SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not 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)

# KORLYM

## Products Affected

- KORLYM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	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.

# LIDOCAINE TRANSDERMAL PATCH

## Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Documentation of post-herpetic neuralgia or diabetic peripheral neuropathy

# LYRICA

## Products Affected

- LYRICA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<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>	Documentation of ONE of the following: (1) a diagnosis of either: (a) neuropathic pain associated with diabetic peripheral neuropathy, (b) neuropathic pain associated with spinal cord injury or (c) fibromyalgia and inadequate response or inability to tolerate duloxetine OR (2) an inadequate response or inability to tolerate gabapentin and documentation of a diagnosis of either of the following: (a) partial-onset epileptic seizures or (b) post-herpetic neuralgia

# MAKENA

## Products Affected

- MAKENA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if part D is medically necessary in individuals at risk of preterm birth when ALL of the following are met: (1) singleton pregnancy (2) not currently in preterm labor (3) there are no other risk factors for preterm birth (such as pregnancy induced hypertension) (4) documented history of singleton spontaneous preterm birth (occurring less than 37 weeks gestation) AND (5) gestational age is between 16 weeks and 37 weeks.

# MAVYRET

## Products Affected

- MAVYRET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Hepatitis C Genotype
<b>Age Restrictions</b>	Deny if less than 18 years
<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

# MODAFINIL

## Products Affected

- *modafinil*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	For NARCOLEPSY or SHIFT WORK DISORDER: Recommended by a neurologist or sleep specialist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	FOR NARCOLEPSY: Documentation of a diagnosis of Narcolepsy. FOR OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS): Documentation that the medication is being used as an adjunct treatment for the underlying obstruction. FOR SHIFT WORK SLEEP DISORDER (SWSD): Documentation that the member has no medical or mental disorder accounting for the symptoms AND the symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness (e.g. time-zone change [jet lag] syndrome)

# MOZOBIL

## Products Affected

- MOZOBIL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Documentation of use in combination with a granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in individuals who have ONE of the following conditions: (1) Non-Hodgkin's lymphoma OR (2) Multiple myeloma

# MULTIPLE SCLEROSIS AGENTS

## Products Affected

- AUBAGIO
- GILENYA ORAL CAPSULE 0.5 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	ONE of the following: (1) inadequate response or inability to tolerate ONE of the following (a) Avonex, (b) Plegridy (c) Betaseron (d) Copaxone (e) Glatopa OR (f) Tecfidera OR (2) continuation of therapy with requested agent

# MYALEPT

## Products Affected

- MYALEPT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	

# NATPARA

## Products Affected

- NATPARA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Deny if patient has a diagnosis of hypoparathyroidism caused by calcium-sensing receptor mutations or post-surgical hypoparathyroidism
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if age less than 18 years
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	

# NON ORAL PAH AGENTS

## Products Affected

- VENTAVIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if 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. RE-AUTHORIZATION CRITERIA: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist.

# NON-ORAL ANTIBIOTICS

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## Products Affected

- AVYCAZ
- DALVANCE
- *daptomycin intravenous solution reconstituted 500 mg*
- *linezolid intravenous solution 600 mg/300ml*
- ORBACTIV
- SIVEXTRO
- SYNERCID

- TEFLARO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 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.

# NON-ORAL CHEMO AGENTS

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## Products Affected

- ABRAXANE
- ADRIAMYCIN INTRAVENOUS SOLUTION
- ADRUCIL INTRAVENOUS SOLUTION 500 MG/10ML
- ALIMTA
- ALIQOPA
- ARRANON
- AVASTIN
- *azacitidine*
- BAVENCIO
- BELEODAQ
- BICNU
- *bleomycin sulfate injection solution reconstituted 30 unit*
- *bortezomib*
- *busulfan*
- BUSULFEX
- *carboplatin intravenous solution 150 mg/15ml*
- *cisplatin intravenous solution 50 mg/50ml*
- *cladribine intravenous solution 10 mg/10ml*
- *clofarabine*
- COSMEGEN
- CYRAMZA
- *cytarabine (pf) injection solution 100 mg/ml*
- *cytarabine injection solution*
- *dacarbazine intravenous solution reconstituted 200 mg*
- *dactinomycin*
- DARZALEX INTRAVENOUS SOLUTION 100 MG/5ML
- *decitabine*
- *dexrazoxane intravenous solution reconstituted 250 mg*
- *docetaxel intravenous concentrate 80 mg/4ml*
- *docetaxel intravenous solution 160 mg/16ml*
- *doxorubicin hcl intravenous solution*
- *doxorubicin hcl liposomal*
- EMLICITI
- *epirubicin hcl intravenous solution 200 mg/100ml*
- ERBITUX INTRAVENOUS SOLUTION 100 MG/50ML
- ERWINAZE INJECTION
- ETOPOPHOS
- *etoposide intravenous solution 100 mg/5ml*
- *fludarabine phosphate intravenous solution reconstituted*
- *fluorouracil intravenous solution 5 gm/100ml*
- FOLOTYN INTRAVENOUS SOLUTION 40 MG/2ML
- *gemcitabine hcl intravenous solution reconstituted 1 gm*
- HALAVEN
- HERCEPTIN
- *idarubicin hcl intravenous solution 10 mg/10ml*
- *ifosfamide intravenous solution reconstituted 1 gm*
- IMFINZI
- *irinotecan hcl intravenous solution 100 mg/5ml*
- ISTODAX (OVERFILL)
- JEVTANA
- KADCYLA
- KEYTRUDA INTRAVENOUS SOLUTION
- KYPROLIS INTRAVENOUS SOLUTION RECONSTITUTED 30 MG, 60 MG
- LARTRUVO
- *melphalan hcl*
- *mitomycin intravenous*
- *mitoxantrone hcl intravenous concentrate 25 mg/12.5ml*
- MUSTARGEN
- MYLOTARG INTRAVENOUS SOLUTION RECONSTITUTED 4.5 MG
- NIPENT
- OPDIVO INTRAVENOUS SOLUTION 100 MG/10ML, 40 MG/4ML
- *oxaliplatin intravenous solution 100 mg/20ml*
- *oxaliplatin intravenous solution reconstituted 100 mg*
- *paclitaxel intravenous concentrate 100 mg/16.7ml*
- PERJETA
- RITUXAN INTRAVENOUS SOLUTION
- SYNRIPO
- TECENTRIQ
- *thiotepa injection*

- TOPOSAR INTRAVENOUS SOLUTION 1 GM/50ML
- *topotecan hcl intravenous solution reconstituted*
- TORISEL
- TREANDA INTRAVENOUS SOLUTION RECONSTITUTED
- TRISENOX INTRAVENOUS SOLUTION 12 MG/6ML
- VECTIBIX INTRAVENOUS SOLUTION 100 MG/5ML
- VELCADE INJECTION
- *vinblastine sulfate intravenous solution*
- VINCASAR PFS
- *vincristine sulfate intravenous*
- *vinorelbine tartrate intravenous solution 50 mg/5ml*
- VYXEOS INTRAVENOUS SUSPENSION RECONSTITUTED 44-100 MG
- YERVOY INTRAVENOUS SOLUTION 50 MG/10ML
- YONDELIS
- ZALTRAP INTRAVENOUS SOLUTION 100 MG/4ML
- ZANOSAR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Indefinite

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Subject to Part B vs Part D review and if 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) Documentation of continuous therapy with the medication requested</p>

# NOXAFIL

## Products Affected

- NOXAFIL ORAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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
<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

# NUCALA

## Products Affected

- NUCALA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if patient is less than 12 years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with pulmonologist or allergy/immunology specialist
<b>Coverage Duration</b>	Initial authorization: 3 months Re-authorization: Remainder of contract year
<b>Other Criteria</b>	Subject to Part B vs Part D review and if part D is medically necessary when there is documentation of all 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, or b) blood eosinophil levels at least 300 cells/microliter within the past 12 months, and 3) Patient is currently treated with high-dose inhaled corticosteroids (ICS) (e.g., greater than or equal to 880mcg 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 Reauthorization criteria: Patient is currently treated with high-dose inhaled corticosteroids (ICS) (e.g., greater than or equal to 880mcg 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

# NUEDEXTA

## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<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>	Documentation of Pseudobulbar affect

# NULOJIX

## Products Affected

- NULOJIX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Transplant recipients who are Epstein-Barr virus seronegative or with unknown Epstein-Barr virus serostatus
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 18 years
<b>Prescriber Restrictions</b>	Prescribed by a nephrologist or transplant specialist
<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 the beneficiary did not receive a transplant from a Medicare-approved facility or were not entitled or qualified for Medicare Part A at the time of the transplant AND when ONE of the following: (1) documentation of continuous therapy with belatacept (Nulojix) OR (2) for prophylaxis of organ rejection in adults receiving a kidney transplant, in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids

# NUPLAZID

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## Products Affected

- NUPLAZID ORAL TABLET 17 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Documentation of inadequate response or inability to tolerate ONE of the following (1) quetiapine or (2) clozapine.

# OCALIVA

## Products Affected

- OCALIVA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with hepatologist or gastroenterologist
<b>Coverage Duration</b>	Initial authorization is 6 months and Reauthorization=Indefinite
<b>Other Criteria</b>	Approved when One of the following is met: (1) Used in combination with ursodeoxycholic acid and patient had suboptimal response to at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, Urso Forte, ursodiol), OR (2) inability to tolerate ursodeoxycholic acid . Reauthorization is approved with documentation of positive clinical response to Ocaliva therapy

# OLUMIANT

## Products Affected

- OLUMIANT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Recommended 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 adalimumab (Humira) AND etanercept (Enbrel) or (2) documentation demonstrating that a trial may be inappropriate

# ORAL ANTIBIOTICS

## Products Affected

- *linezolid oral*
- SIVEXTRO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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.

# ORAL CHEMO AGENTS

## Products Affected

- AFINITOR
- AFINITOR DISPERZ
- ALECENSA
- ALUNBRIG
- *bexarotene*
- BOSULIF
- CABOMETYX
- CALQUENCE
- CAPRELSA
- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)
- COTELLIC
- ERIVEDGE
- ERLEADA
- FARYDAK
- GILOTRIF
- GLEOSTINE ORAL CAPSULE 10 MG, 100 MG, 40 MG
- IBRANCE
- ICLUSIG
- IDHIFA
- *imatinib mesylate*
- IMBRUVICA
- INLYTA
- IRESSA
- JAKAFI
- KISQALI 200 DOSE
- KISQALI 400 DOSE
- KISQALI 600 DOSE
- KISQALI FEMARA 200 DOSE
- KISQALI FEMARA 400 DOSE
- KISQALI FEMARA 600 DOSE
- LENVIMA 10 MG DAILY DOSE
- LENVIMA 14 MG DAILY DOSE
- LENVIMA 18 MG DAILY DOSE
- LENVIMA 20 MG DAILY DOSE
- LENVIMA 24 MG DAILY DOSE
- LENVIMA 8 MG DAILY DOSE
- LONSURF
- LYNPARZA
- MEKINIST
- NERLYNX
- NEXAVAR
- NINLARO
- ODOMZO
- POMALYST
- REVLIMID
- RUBRACA
- RYDAPT
- SPRYCEL
- STIVARGA
- SUTENT
- TAFINLAR
- TAGRISSO
- TARCEVA
- TASIGNA
- THALOMID
- TYKERB
- VENCLEXTA
- VENCLEXTA STARTING PACK
- VERZENIO
- VOTRIENT
- XALKORI
- XTANDI
- YONSA
- ZEJULA
- ZELBORAF
- ZOLINZA
- ZYDELIG
- ZYKADIA
- ZYTIGA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	

PA Criteria	Criteria Details
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	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) Documentation of continuous therapy with the medication requested

# ORAL PAH AGENTS

## Products Affected

- LETAIRIS
- OPSUMIT
- ORENITRAM
- TRACLEER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 month for initial authorization and 12 months for renewal authorizations
<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. RE-AUTHORIZATION CRITERIA: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist.

# ORENCIA IV

## Products Affected

- ORENCIA INTRAVENOUS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 6 years
<b>Prescriber Restrictions</b>	Medication is being recommended by a rheumatologist
<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 given in the home setting or long term care facility and is considered medically necessary when there is documentation of adult rheumatoid arthritis , psoriatic arthritis, or juvenile idiopathic arthritis with an inadequate response to at least ONE disease-modifying antirheumatic drug (DMARDs) such as methotrexate

# ORENCIA SQ

## Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SOLUTION  
 PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Medication is being recommended by a rheumatologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Documentation of either (1) inadequate response or inability to tolerate adalimumab (Humira) and etanercept (Enbrel) OR documentation demonstrating that a trial may be inappropriate

# ORKAMBI

## Products Affected

- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 6
<b>Prescriber Restrictions</b>	
<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

# PALYNZIQ

## Products Affected

- PALYNZIQ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	
<b>Coverage Duration</b>	Initial: 6 months, Continuation: Indefinite
<b>Other Criteria</b>	CONTINUATION CRITERIA: Documentation of a positive clinical response to Palynziq therapy

## PART D VS EXCLUDED

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### Products Affected

- AURYXIA
- INTRAROSA
- OSPHENA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	

# PDE INHIBITOR AGENTS FOR PAH

## Products Affected

- ADCIRCA
- REVATIO ORAL SUSPENSION  
RECONSTITUTED

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 RE-AUTHORIZATION CRITERIA: Documentation of stabilization or improvement as evaluated by a cardiologist or pulmonologist.

# PICATO

## Products Affected

- PICATO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One Month
<b>Other Criteria</b>	Documentation of BOTH of the following: (1) diagnosis of actinic keratosis AND (2) inadequate response or inability to tolerate one previous therapy (i.e. diclofenac gel 3%, imiquimod, flurouracil).

# PRALUENT

## Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION  
PEN-INJECTOR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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 Re-authorization criteria: approved for 12 months if there is documentation of sustained reduction in LDL-C from start of therapy

# PROCYSBI

## Products Affected

- PROCYSBI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Hypersensitivity to penicillamine
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 2 years
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months for initial authorization and 6 months for renewal authorization
<b>Other Criteria</b>	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

# PROLIA

## Products Affected

- PROLIA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if 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.

# PROVIGIL/NUVIGIL

## Products Affected

- *armodafinil*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	For NARCOLEPSY or SHIFT WORK SLEEP DISORDER (SWSD): Recommended by a neurologist or sleep specialist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Documentation of inadequate response or inability to tolerate generic modafinil AND one of the following (1) FOR NARCOLEPSY: Documentation of a diagnosis of Narcolepsy. (2) FOR OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS): Documentation that the medication is being used as an adjunct treatment for the underlying obstruction. (3) FOR SHIFT WORK SLEEP DISORDER (SWSD): Documentation that the member has no medical or mental disorder accounting for the symptoms AND the symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness (e.g. time-zone change [jet lag] syndrome)

# PULMONARY FIBROSIS AGENTS

## Products Affected

- ESBRIET
- OFEV

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by an appropriate specialist such as pulmonologist or lung transplant
<b>Coverage Duration</b>	12 months initial and reauthorization
<b>Other Criteria</b>	Diagnosis of idiopathic pulmonary fibrosis confirmed by high resolution CT scan or biopsy REAUTHORIZATION CRITERIA: 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

# QUALAQUIN

## Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Diagnosis of uncomplicated plasmodium falciparum malaria

# RADICAVA

## Products Affected

- RADICAVA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by a neurologist experienced in treating ALS
<b>Coverage Duration</b>	Initial authorization: 6 months, Reauthorization: 6 months
<b>Other Criteria</b>	ALL of the following (1) Diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) per the revised El Escorial World Federation of Neurology criteria (2) Time from symptom onset is 2 years or less (3) Normal respiratory function as defined as forced vital capacity (FVC) of greater than or equal to 80% (4) Scores of 2 points or greater on each individual item of the ALS Functional Rating Scale-revised (ALSFRRS-R) Reauthorization criteria: member is not permanently ventilator dependent

# RAVICTI

## Products Affected

- RAVICTI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# REMODULIN

## Products Affected

- REMODULIN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by pulmonologist or cardiologist
<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) diagnosis of pulmonary arterial hypertension (World Health Organization group 1) (2) mean pulmonary artery pressures greater than or equal to 25 mm Hg at rest by right heart catheterization or echocardiography and (3) NYHA functional class II through IV symptoms

# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	<p>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) on any statin 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. Re-authorization criteria: approved for 12 months if there is documentation of sustained reduction in LDL-C from baseline</p>

# RESPIRATORY ENZYMES

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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)

# SAMSCA

## Products Affected

- SAMSCA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not 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 and BOTH of the following (1) ONE of the following (a) serum sodium less than 125meq/L or (b) serum sodium 125-135 meq/L with symptoms (2) inadequate response or inability to tolerate therapies to control hyponatremia (ie fluid restriction, diuretics, demeclocycline)

# SAVELLA

## Products Affected

- SAVELLA
- SAVELLA TITRATION PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Deny if less than 18 years
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	Diagnosis of fibromyalgia and inadequate response or inability to tolerate generic duloxetine

# SEROSTIM

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## Products Affected

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

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Deny if not prescribed by HIV specialist
Coverage Duration	48weeks
Other Criteria	Wasting or cachexia associated with HIV

# SIGNIFOR

## Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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>	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

# SIGNIFOR LAR

## Products Affected

- SIGNIFOR LAR INTRAMUSCULAR  
SUSPENSION RECONSTITUTED ER 20  
MG, 40 MG, 60 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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>	Subject to Part B vs Part D review and if part D is medically necessary there is documentation of a diagnosis of acromegaly in patients with an inadequate response to surgery or who are not candidates for surgery

# SILDENAFIL

## Products Affected

- *sildenafil citrate intravenous*
- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# SILIQ

## Products Affected

- SILIQ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not 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

# SIMPONI

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not prescribed by Rheumatologist, gastroenterologist, or dermatologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Ankylosing Spondylitis or Psoriatic Arthritis: inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate. 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 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

# SIMPONI ARIA

## Products Affected

- SIMPONI ARIA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not prescribed by Rheumatologist.
<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) inadequate response to methotrexate AND and (2) concurrent use with methotrexate

# SIRTURO

## Products Affected

- SIRTURO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Sirturo (bedaquiline) will be administered by directly observed therapy (DOT).
<b>Age Restrictions</b>	Deny if less than 18 years
<b>Prescriber Restrictions</b>	Recommended 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.

# STELARA

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<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>	Deny if not prescribed by Dermatologist, Gastroenterologist, or Rheumatologist
<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 there is an inadequate response or inability to tolerate to both adalimumab (Humira) AND etanercept (Enbrel) or documentation demonstrating that a trial may be inappropriate

# STRENSIQ

## Products Affected

- STRENSIQ SUBCUTANEOUS SOLUTION  
40 MG/ML, 80 MG/0.8ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For patients requesting 80mg/0.8ml vial: patient's weight is greater than or equal to 40kg
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	

# SYLATRON

## Products Affected

- SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	autoimmune hepatitis, hepatic decompensation
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Deny if not prescribed by dermatologist or oncologist
<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 ONE of the following inclusion criteria is met:(1) use for adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy OR (2) documentation of continuous therapy with Peginterferon alfa-2b (Sylatron)

# SYLVANT

## Products Affected

- SYLVANT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Subject to Part B vs Part D review and if part D is medically necessary when there is a diagnosis of multicentric Castleman disease (MCD) and BOTH HIV negative and human herpesvirus-8 (HHV-8) negative

# SYMDEKO

## Products Affected

- SYMDEKO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if age less than 12 years
<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.

# SYNAGIS

## Products Affected

- SYNAGIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Max 5 doses

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Subject to Part B vs Part D review and if part D is medically necessary for the prophylaxis of respiratory syncytial virus (RSV) when ONE of the following is met: (1) Infants born before 29 wks, 0 days gestation and are less than 12 mos at start of RSV season (2) Infants and children with chronic lung disease (CLD) of prematurity defined as gestational age (GA) less than 32 wks, 0 days and a requirement for greater than 21% oxygen for at least 28 days after birth and one of the following: (a) during the first year of life (b) during the second year of life who require medical therapy for CLD within the six mos before start of the RSV season. (Medical therapy includes any of the following: requirement for supplemental oxygen, use of bronchodilators, diuretic therapy or corticosteroid) (3) Infants with congenital heart disease (CHD) who are 12 mos of age or younger at the start of the RSV season and meet the following criteria: (a) hemodynamically significant acyanotic CHD and receiving medication for congestive heart failure and will require a cardiac surgery procedure (b) hemodynamically significant cyanotic CHD after consultation with a pediatric cardiologist (c) diagnosis of moderate-to-severe pulmonary hypertension (4) Infants 12 mos of age or younger at start of RSV season with either of the following: (a) congenital abnormalities of the airway (b) neuromuscular disease that compromises mobilization of respiratory secretions (5) Infants and children younger than 24 mos of age who are profoundly immunocompromised (e.g., due to transplantation or chemotherapy) during the RSV season (6) Infants and children younger than 24 months with cystic fibrosis (CF) when at least one of the following: (a) Nutritional compromise, (b) Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persists when stable). CRITERIA FOR ONE ADDITIONAL POST OP DOSE: Documentation of ALL of the following: (1) age less than 24 mos (2) currently receiving palivizumab (3) medically stable (4) meet the above criteria for immune prophylaxis AND (5) have undergone ONE of the following procedures during the current RSV season: (1) Surgical procedures that use cardiopulmonary bypass (2) Cardiac transplantation. MAX OF 5 MONTHLY DOSES.</p>

# TALTZ

## Products Affected

- TALTZ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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
<b>Prescriber Restrictions</b>	Deny if not prescribed by rheumatologist or 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

# TAVALISSE

## Products Affected

- TAVALISSE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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.

# TESTOSTERONE PRODUCTS

## Products Affected

- *testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 25 mg/2.5gm (1%), 50 mg/5gm (1%)*
- *testosterone transdermal solution*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Normal prolactin level, low (morning) testosterone level [For new starts only]
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Remainder of contract year
<b>Other Criteria</b>	Documentation of ONE of the following (1) negative history of prostate and breast cancer OR (2) history of prostate cancer status post prostatectomy and documentation that the risk versus benefit has been assessed

# TOPICAL RETINOID PRODUCTS

## Products Affected

- *adapalene external cream*
- *adapalene external gel*
- *adapalene-benzoyl peroxide*
- AVITA
- *tretinoin external*
- *tretinoin microsphere*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	

# TREMFYA

## Products Affected

- TREMFYA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not 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

# TYSABRI

## Products Affected

- TYSABRI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use of immunosuppressants or TNF inhibitors
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 18 years
<b>Prescriber Restrictions</b>	Deny if not prescribed by neurologist or gastroenterologist
<b>Coverage Duration</b>	End of contract year
<b>Other Criteria</b>	Subject to Part B vs Part D review and if part D is medically necessary when there is documentation of ONE of the following: (1) diagnosis of Crohn's disease with an inadequate response or inability to tolerate BOTH of the following: (a) ONE of the following: Corticosteroids, Aminosalicylates, Immunomodulators (ex. Azathioprine, 6-mercaptopurine), AND (b) ONE tumor necrosis factor-alpha (TNF-alpha) OR (2) diagnosis of Multiple sclerosis and inadequate response or inability to tolerate ONE alternative MS therapy (ie Avonex, Betaseron, Copaxone, Tecfidera, etc)

# UPTRAVI

## Products Affected

- UPTRAVI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Deny if not 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.

# VALCHLOR

## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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

# VECAMYL

## Products Affected

- VECAMYL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# XELJANZ

## Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Recommended by a Gastroenterologist or Rheumatologist
<b>Coverage Duration</b>	Indefinite
<b>Other Criteria</b>	Inadequate response or inability to tolerate methotrexate AND ONE of the following: (1) inadequate response or inability to tolerate adalimumab (Humira) AND etanercept (Enbrel) or (2) documentation demonstrating that a trial may be inappropriate

# XENAZINE/AUSTEDO

## Products Affected

- AUSTEDO
- *tetrabenazine*

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	Tetrabenazine (Xenazine) or Deutetrabenazine (Austedo) is approved when BOTH of the following are met: 1. Used for the treatment of chorea associated with Huntington's disease, and 2. Prescribed by or in consultation with a neurologist

# XGEVA

## Products Affected

- XGEVA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Prevention of skeletal-related events in patients with multiple myeloma
<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 necessary when there is documentation of ONE of the following diagnoses: (1) 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

# XOLAIR

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 and if part D is medically necessary FOR DIAGNOSIS OF MODERATE TO SEVERE PERSISTENT 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 700 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 or inability to tolerate ONE second-generation antihistamine at the maximum recommended doses 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

# XYREM

## Products Affected

- XYREM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	recommended by a neurologist or sleep specialist
<b>Coverage Duration</b>	3 months (initial and reauthorization)
<b>Other Criteria</b>	Documentation of 1) cataplexy in narcolepsy OR 2) excessive daytime sleepiness in narcolepsy with inadequate response or inability to modafanil. 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

# ZAVESCA

## Products Affected

- *miglustat*
- ZAVESCA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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>	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).

# ZINPLAVA

## Products Affected

- ZINPLAVA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Deny if less than 18 years old
<b>Prescriber Restrictions</b>	Infectious disease specialist or gastroenterologist
<b>Coverage Duration</b>	one month
<b>Other Criteria</b>	Subject to Part B vs Part D review and if part D is medically necessary when there is documentation of ALL of the following: (1) confirmed diagnosis of C. difficile infection (2) Patient is at high risk for recurrence of C. difficile infection as documented by any of the following: (a) age $\geq$ 65 years, (b) use of systemic non-C. difficile antibiotics, (c) use of proton pump inhibitors, (d) underlying comorbidities that will predispose member to recurrence of C. difficile infection (eg immunocompromised, prior episode of C. difficile infection, etc), (e) recent hospitalization (3) bezlotoxumab will be administered in combination with standard antibiotics to reduce recurrent CDI (ie metronidazole, vancomycin administered enterally, fidaxomicin).

# ZORBTIVE

## Products Affected

- ZORBTIVE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 weeks
<b>Other Criteria</b>	Used in conjunction with optimal management for short bowel syndrome, including specialized nutrition support

# ZURAMPIC

## Products Affected

- ZURAMPIC

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	Documentation of concurrent use of a xanthine oxidase inhibitor

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