

## ABILIFY MYCITE

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### Products Affected

- Abilify Mycite Maintenance Kit
- Abilify Mycite Starter Kit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The following criteria applies to members who newly start on the drug: documentation of the medical necessity of tracking compliance with the prescribed treatment regimen.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# ACTEMRA

## Products Affected

- Actemra INJ 162MG/0.9ML
- Actemra Actpen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Rheumatoid arthritis (RA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 2) Juvenile idiopathic arthritis (JIA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count. 3) Lung disease with systemic sclerosis, renewal: documentation of a reduction in decline in pulmonary function.
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA, temporal arteritis: rheumatologist. Lung disease: pulmonologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	RA initial: failure of methotrexate and at least one other DMARD such as leflunomide, sulfasalazine, or hydroxychloroquine. Polyarticular juvenile idiopathic arthritis initial: failure of an 8 week trial of methotrexate.

# ACTHAR HP

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## Products Affected

- Acthar
- Cortrophin INJ 80UNIT/ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Use of corticotropin intravenously. Corticotropin should not be used in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or active peptic ulcer disease, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. Corticotropin is contraindicated in patients under the age of 2 with suspected congenital infections and for patients who also have adrenocortical insufficiency or adrenocortical hyperfunction.
<b>Required Medical Information</b>	Medical record documentation of one of the following conditions: 1) Infantile spasms, 2) Acute exacerbation of multiple sclerosis, 3) Exacerbation of rheumatic disorders including psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, 4) Exacerbation of or maintenance for collagen diseases including systemic lupus erythematosus, systemic dermatomyositis, 5) Dermatologic diseases including severe erythema multiforme, Stevens-Johnson Syndrome, 6) Allergic states such as serum sickness, 7) Ophthalmic diseases including keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, 7) Respiratory diseases such as symptomatic sarcoidosis or 8) Edematous condition from nephrotic syndrome or lupus erythematosus.
<b>Age Restrictions</b>	For infantile spasms: age less than 2 years.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Infantile spasms: until two years of age. All others: 1 month.
<b>Other Criteria</b>	For steroid responsive conditions, conditions number 2 to 7 listed in the Required Medical Information section: medical record documentation of failure of corticosteroid therapy in the last 30 days or reason why corticosteroids cannot be used.

# ACTIMMUNE

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## Products Affected

- Actimmune INJ 100MCG/0.5ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	T-cell lymphoma
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Prior authorization criteria does not apply to members already established on Actimmune for the treatment of T-cell lymphoma. 1. The use of Actimmune for T-cell lymphoma must be supported by Micromedex, AHFS-Drug Information, NCCN Compendium, Clinical Pharmacology, Lexi-Drugs, or acceptable medical journals.

# ADALIMUMAB

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## Products Affected

- Adalimumab-aaty 1-pen Kit
- Adalimumab-aaty 2-pen Kit
- Adalimumab-aaty 2-syringe Kit
- Adalimumab-aaty Cd/uc/hs Starter
- Adalimumab-adbm
- Adalimumab-adbm Crohns/uc/hs Starter
- Adalimumab-adbm Psoriasis/uveitis Starter
- Adalimumab-adbm Starter Package For Crohns Disease/uc/hs
- Adalimumab-adbm Starter Package For Psoriasis/uveitis
- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Crohn's disease (CD) renewal: a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. 2) Rheumatoid arthritis (RA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 3) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count. 4) Ankylosing spondylitis (AS) renewal: improved functioning and/or signs and symptoms of AS. 5) Juvenile idiopathic arthritis (JIA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count. 6) Plaque psoriasis (PsO) initial: involvement of at least 3% of body surface area or hand, foot, face, scalp, or genital involvement. PsO renewal: improvement in affected BSA, plaque severity and/or functioning. 7) Ulcerative Colitis (UC) renewal: medical record documentation of treatment response such as decrease in bloody stools per day, elimination of signs of toxicity, or clinical remission. 8) Hidradenitis suppurativa (HS) initial: moderate to severe disease evident by documentation of Hurley Stage II or III and at least 3 abscesses or inflammatory nodules. HS renewal: medical record documentation of a reduction in nodules or abscesses. 9) Uveitis initial: documentation of non-infectious, intermediate, posterior or panuveitis. Renewal: documentation that treatment response is being monitored for the following development of new inflammatory chorioretinal and/or inflammatory retinal vascular lesions, anterior chamber cell grade or vitreous haze, or visual acuity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: dermatologist or rheumatologist. Plaque psoriasis or hidradenitis suppurativa: dermatologist. Crohn's disease and ulcerative colitis: Gastroenterologist. Uveitis: Ophthalmologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	RA initial, failure of one of the following: methotrexate, leflunomide, sulfasalazine, or hydroxychloroquine. AS initial: failure of one non-

	steroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac. JIA initial: failure of an 8 week trial of methotrexate. PsO Initial: failure of 1) one topical agent such as a corticosteroid (i.e. betamethasone or clobetasol), calcipotriene, tacrolimus, or tazarotene (requires prior authorization), and 2) methotrexate or cyclosporine.
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# ADBRY

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## Products Affected

- Adbry

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Atopic dermatitis initial (AD): body surface area involvement of at least 10% at baseline. 2) AD renewal criteria: medical record documentation of a positive treatment response such as a reduction in body surface area involvement, improvement in itching, improvement in functional ability, reduction in the Investigator Global Assessment or Eczema Area and Severity Index from baseline.
Age Restrictions	N/A
Prescriber Restrictions	Prescribing restricted to a dermatologist, allergist, or immunologist or in consultation with.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Atopic dermatitis: failure of or contraindication to 1) one of the following very high potency topical steroids: augmented betamethasone, clobetasol or halobetasol and 2) tacrolimus ointment,

# ADEMPAS

## Products Affected

- Adempas

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: 1) For patients with WHO Group 4 pulmonary arterial hypertension - chronic thromboembolic pulmonary arterial hypertension: failure of surgical treatment or would not be a candidate for surgical treatment.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist or cardiologist
Coverage Duration	Lifetime
Other Criteria	Initial criteria for patients with WHO Group 1 pulmonary arterial hypertension: Medical record documentation of failure of or would be a poor candidate for the following: 1) A phosphodiesterase type 5 (PDE-5) inhibitor such as sildenafil or tadalafil and 2) An endothelin receptor antagonist such as ambrisentan or bosentan.

# AGAMREE

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## Products Affected

- Agamree

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: genetic testing results confirming a diagnosis of Duchenne muscular dystrophy. Renewal criteria: documentation of a positive treatment response (e.g. pulmonary function, muscle strength, functional ability, walk tests).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a specialist in Duchenne Muscular Dystrophy or neuromuscular disorders.
Coverage Duration	12 months
Other Criteria	Failure of prednisone and deflazacort (requires PA).

# AIMOVIG

## Products Affected

- Aimovig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: 1) Episodic migraine: 4-14 headache days per month, 2) Chronic migraines: 15 or more headache days per month with at least 8 days of migraines for 3 months. Migraine renewal criteria: documentation of treatment response including decrease in the number of migraine days, less migraine episodes, decreased abortive medication usage, or emergency room visits related to migraine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime
Other Criteria	1) Episodic Migraine prophylaxis and chronic migraine prophylaxis: failure of propranolol and topiramate.

## ALDURAZYME

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### Products Affected

- Aldurazyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Diagnostic confirmation by presence of glycosaminoglycans (GAG) in the urine, deficiency in a-L-iduronidase enzyme activity, or genetic testing, and 2) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization of disease progression, such as improvement in percent predicted FVC, improvement in 6-minute walk test, reduction in urinary GAG levels, or reduction in liver size.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	Dosing consistent with product label: 0.58 mg/kg IV once weekly.

# ALOSETRON

## Products Affected

- Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Constipation. 2) Intestinal obstruction, stricture, toxic megacolon, GI perforation and/or adhesions. 3) Ischemic colitis, impaired intestinal circulation. 4) Severe hepatic impairment. 5) Diverticulitis. 6) Hypercoaguable state. 6) Thrombophlebitis. 7) Crohn's disease or ulcerative colitis. 8) Concomitant use with apomorphine or fluvoxamine.
Required Medical Information	Initial: Medical record documentation of predominant symptom is severe diarrhea lasting at least 6 months and defined as frequent and severe abdominal pain/discomfort, frequent bowel urgency or fecal incontinence, or disability or restriction of daily activities due to IBS. Renewal: Medical record documentation of a significant reduction in diarrhea frequency and abdominal pain and/or improvement in quality of life during the 8 week trial.
Age Restrictions	Age at least 18 years.
Prescriber Restrictions	N/A
Coverage Duration	Initial: 8 weeks. Renewal: Lifetime.
Other Criteria	Failure of loperamide and dicyclomine.

# ALYFTREK

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## Products Affected

- Alyftrek

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of a diagnosis of cystic fibrosis with at least one F508del mutation or has a mutation that is responsive to the drug confirmed using an FDA-cleared cystic fibrosis mutation test. Renewal: Medical record documentation of treatment response such as an improvement in FEV1, reduction in pulmonary exacerbation, or improvement in respiratory symptoms.
Age Restrictions	6 years of age and older.
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Initial: Trial of Trikafta in patients with at least one F508del mutation or a Trikafta-responsive mutation.

## AMBRISENTAN

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### Products Affected

- Ambrisentan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pregnancy
Required Medical Information	Documentation of WHO Class II-IV.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist or Cardiologist
Coverage Duration	Lifetime
Other Criteria	N/A

# APOKYN

## Products Affected

- Apomorphine Hydrochloride INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: Documentation that the patient's off time has been reduced with apomorphine.
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 months. Renewal: Lifetime.
Other Criteria	Initial: Documentation of failure of maximum tolerable doses of oral levodopa/carbidopa and one of the following: selegiline, ropinirole, pramipexole, tolcapone and entacapone.

# APTOM

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## Products Affected

- Aptiom
- Eslicarbazepine Acetate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Failure of 1) oxcarbazepine and 2) One of the following: carbamazepine, phenytoin, topiramate, divalproex, felbamate, tiagabine, lamotrigine, gabapentin, zonisamide, lacosamide, levetiracetam.

## AQNEURSA

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### Products Affected

- Aqneursa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: a) confirmation of a diagnosis of Niemann-Pick disease type C (NPC) by genetic testing, b) documentation of neurologic symptoms due to NPC, and c) documentation of weight at least 15kg.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or neurologist.
Coverage Duration	Lifetime.
Other Criteria	N/A

# ARALAST

## Products Affected

- Aralast Np INJ 1000MG, 500MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) documented ZZ or Z/null AAT deficiency and 2) AAT serum level less than or equal to 11 micromoles/L or 50mg/dL and 3) moderate emphysema and/or FEV1 less than 80% and 4) the provider has outlined specific, measurable treatment goals such as slowing of FEV1 decline or lack of disease progression. Renewal: documentation patient is meeting treatment goals such as slowing FEV1 decline or lack of disease progression.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	N/A

# ARCALYST

## Products Affected

- Arcalyst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Deficiency of Interleukin-1 Receptor Antagonist (DIRA) renewal: documentation of positive clinical response, such as low disease activity or improvement in signs and symptoms. 2) Recurrent pericarditis, renewal: documentation that pericarditis has not recurred. 3) All others indications: Renewal criteria: Medical record documentation of significant improvements in signs and symptoms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	For Deficiency of Interleukin-1 Receptor Antagonist (DIRA): failure of Kineret (requires PA).

## ARIKAYCE

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### Products Affected

- Arikayce

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation that Arikayce will be used as part of combination antibacterial drug regimen, and either positive sputum culture or lack of clinical signs of improvement (such as anemia, fever, or lack of reduction in nodule size).
Age Restrictions	Age at least 18 years
Prescriber Restrictions	Infectious disease specialist, HIV specialist or pulmonologist
Coverage Duration	6 months
Other Criteria	Failure of at least 6 consecutive months of a multidrug regimen (such as combination of the following agents: azithromycin or clarithromycin, ethambutol, rifabutin, clofazimine).

# ARISTADA

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## Products Affected

- Aristada
- Aristada Initio

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The following criteria applies to members who newly start on the drug: documentation that the patient is currently taking oral Abilify and prescriber wishes to switch to the injection to improve compliance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# ARMODAFINIL

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## Products Affected

- Armodafinil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: documentation of significant improvement in daytime sleepiness and functioning.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: lifetime.
Other Criteria	N/A

# ASTAGRAF

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## Products Affected

- Astagraf XL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	To prevent or treat an organ transplant rejection, Part B versus D determination will be made to determine coverage. If the drug is to be covered by Part D and the patient is newly started on Astagraf, failure of tacrolimus immediate release or reason why tacrolimus immediate release cannot be used is required.

# ATTRUBY

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## Products Affected

- Attruby

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation confirming the diagnosis of either wild-type or hereditary transthyretin amyloid cardiomyopathy (ATTRwt-CM or hATTR-CM).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	Lifetime
Other Criteria	N/A

# AUSTEDO

## Products Affected

- Austedo

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Excluded in patients with suicidality, hepatic impairment, inadequately treated depression, concomitant use of MAOIs and reserpine.
<b>Required Medical Information</b>	Renewal criteria: 1) For Huntington's disease (HD): medical record documentation of a clinical response such as improvement in chorea, ability to perform activities of daily living, reduction in falls, and increase in quality of life. 2) For tardive dyskinesia (TD): medical record documentation of treatment response such as a reduction in the AIMS score from baseline, improvement in involuntary movement, or improvement in functional ability
<b>Age Restrictions</b>	For tardive dyskinesia (TD): 18 years and older
<b>Prescriber Restrictions</b>	HD: prescribed by or in consultation with a neurologist. TD: prescribed by or in consultation with a neurologist, movement disorder specialist or a psychiatrist.
<b>Coverage Duration</b>	HD Initial: 3 months. TD Initial: 6 months. Renewal for HD and TD: 12 months.
<b>Other Criteria</b>	Initial criteria for HD: failure of or contraindication to tetrabenazine (requires prior authorization). Initial criteria for TD: failure of or contraindication to tetrabenazine and Ingrezza (both require prior authorization).

# AUVELITY

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## Products Affected

- Auvelity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on Auvelity: medical record documentation of failure of a) bupropion and b) an SSRI or SNRI such as sertraline, fluoxetine, escitalopram, paroxetine, venlafaxine, duloxetine.

# BENLYSTA

## Products Affected

- Benlysta

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Severe active CNS lupus or used in combination with other biologics or IV cyclophosphamide
<b>Required Medical Information</b>	A) Systemic lupus erythematosus initial criteria: 1) Medical record documentation of a diagnosis of systemic lupus erythematosus (SLE) and is auto-antibody positive as defined as Antinuclear antibody (ANA titer) greater than or equal to 1:80 or anti-double stranded DNA antibody (Anti-dsDNA) greater than or equal to 30 IU/ml. 2) Receiving standard therapy including NSAIDs, antimalarials, corticosteroids or immunosuppressants. Renewal criteria: medical record documentation of treatment response such as an improvement in the SELENA-SLEDAI score or no worsening of disease activity. B) Active lupus nephritis initial criteria: 1) Medical record documentation of a diagnosis of active lupus nephritis. 2) Receiving standard therapy including corticosteroids or immunosuppressants. Renewal: medical record documentation of treatment response such as stabilization of eGFR or no worsening of disease activity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Rheumatologist or nephrologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# BENZNIDAZOLE

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## Products Affected

- Benznidazole

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Chagas disease caused by T. cruzi confirmed by detection of T. cruzi trypomastigotes on microscopy, detection of T. cruzi DNA by PCR assay, or 2 positive diagnostic serologic tests using two different techniques and antigens showing IgG antibodies to T. cruzi.
Age Restrictions	Age at least 2 to 12 years
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist or cardiologist
Coverage Duration	60 days
Other Criteria	N/A

# BEXSERO

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## Products Affected

- Bexsero INJ 0.5ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age 10-25 years
Prescriber Restrictions	N/A
Coverage Duration	Series of 2 doses in 2 months.
Other Criteria	N/A

# BOSENTAN

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## Products Affected

- Bosentan
- Tracleer TBSO

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Concomitant administration with cyclosporine A or glyburide. 2) Pregnancy.
Required Medical Information	Documentation of New York Heart Association (NYHA) Class II-IV.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist or Cardiologist
Coverage Duration	Lifetime
Other Criteria	The following does not apply to pediatric members with idiopathic/congenital pulmonary arterial hypertension: Failure of or contraindication to sildenafil or tadalafil (both require prior authorization).

# BOTULINUM TOXIN

## Products Affected

- Botox
- Xeomin

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Chronic migraine (For Botox only): a) Initial: at least 15 days of headache lasting 4 hours a day or longer. b) Renewal: documentation of treatment response including decrease in the number of migraine days, less migraine episodes, decreased abortive medication usage, or emergency room visits related to migraine. 2. Urinary incontinence (For Botox only) renewal criteria: documentation of treatment response including a decrease in the number of incontinence episodes or frequency. 3. Chronic sialorrhea: Renewal criteria (For Xeomin only): documentation of treatment response such as an improvement in drooling severity, drooling frequency, or improvement in the Global Impression of Change Scale. 4) Renewal criteria for all other diagnoses: documentation of treatment response including a decrease in the severity of dystonia, decrease in pain, or decrease in disability.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Xeomin (chronic sialorrhea): 12 months, 3 dose series. All other diagnoses: 12 months, 4 dose series
Other Criteria	1) Migraine prophylaxis (For Botox only): failure of propranolol and topiramate. 2) Urinary incontinence (For Botox only): failure of two oral anticholinergics such as oxybutynin, tolterodine, or solifenacin.

# BRIVIACT

## Products Affected

- Briviact

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on Briviact tablets or suspension. For tabs: medical record documentation of failure of 1) levetiracetam and 2) one of the following: carbamazepine, phenytoin, topiramate, divalproex, felbamate, tiagabine, lamotrigine, gabapentin, oxcarbazepine, lacosamide, or zonisamide. For suspension: 1) medical record documentation of failure of a) levetiracetam suspension and b) one of the following suspensions or solutions: carbamazepine, phenytoin, felbamate, oxcarbazepine, gabapentin, or lacosamide, and 2) inability to swallow oral dosage forms.

# BRONCHITOL

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## Products Affected

- Bronchitol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Failure of bronchitol tolerance test.
Required Medical Information	Initial: confirmation of a diagnosis of cystic fibrosis.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	Lifetime
Other Criteria	N/A

# BUPHENYL

## Products Affected

- Sodium Phenylbutyrate POWD 3GM/TSP
- Sodium Phenylbutyrate TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Use as emergency treatment of acute hyperammonemia.
Required Medical Information	Initial: Medical record documentation of diagnostic confirmation by plasma quantitative amnio acid analysis or urinary orotic acid testing or enzyme activity from a liver biopsy or genetic testing. Renewal: Medical record documentation of stabilization of disease progression.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	Dosing consistent with product label: Usual total daily dose is 450-600mg/kg/day in patients weighing less than 20kg, or 9.9-13.0 G/m2/day in larger patients. Maximum dose is 20 G/day.

# BUPRENORPHINE PATCH

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## Products Affected

- Buprenorphine PTWK

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Failure of morphine sulfate ER.

# BYLVAY

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## Products Affected

- Bylvay
- Bylvay (pellets)

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of pruritis associated with progressive familial intrahepatic cholestasis or associated with Alagille syndrome. Renewal: Medical record documentation of clinical benefit such as decrease in pruritis or improvement in quality of life.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months
Other Criteria	N/A

# CABLIVI

## Products Affected

- Cablivi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Medical record support of a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP). 2) Documentation that Cablivi will be used in combination with plasma exchange. Renewal: Documented signs of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present.
Age Restrictions	N/A
Prescriber Restrictions	Hematologist
Coverage Duration	Initial: 90 days. Renewal-receiving plasma exchange: 90 days. Renewal-post plasma exchange: 58 days.
Other Criteria	N/A

# CAMZYOS

## Products Affected

- Camzyos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) medical record documentation of NYHA class II or III obstructive hypertrophic cardiomyopathy and 2) documentation of left ventricular ejection fraction of greater than or equal to 55%. Renewal: 1) documentation of left ventricular ejection fraction of greater than 50% and 2) improvement in symptoms or functioning.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a cardiologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# CANCER DRUGS

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## Products Affected

- Abiraterone Acetate
- Abirtega
- Abraxane
- Akeega
- Alecensa
- Aliqopa
- Alunbrig
- Augtyro
- Avastin
- Ayvakit
- Balversa
- Bavencio
- Beleodaq
- Bendamustine Hydrochloride INJ  
100MG, 25MG
- Besremi
- Bexarotene
- Bortezomib INJ 3.5MG
- Bosulif
- Braftovi CAPS 75MG
- Brukinsa
- Busulfan
- Cabometyx
- Calquence
- Caprelsa
- Carmustine INJ 100MG
- Clofarabine
- Cometriq
- Copiktra
- Cotellic
- Cyramza
- Dacarbazine INJ 200MG
- Dactinomycin
- Danziten
- Darzalex
- Darzalex Faspro
- Dasatinib
- Daunorubicin Hydrochloride INJ  
20MG/4ML
- Daurismo
- Docetaxel INJ 160MG/16ML,  
160MG/8ML, 20MG/2ML,  
20MG/ML, 80MG/4ML, 80MG/8ML
- Doxorubicin Hcl INJ 2MG/ML

- Doxorubicin Hydrochloride INJ 10MG
- Doxorubicin Hydrochloride Liposomal
- Empliciti
- Erbitux INJ 100MG/50ML
- Eribulin Mesylate
- Erivedge
- Erleada
- Erlotinib Hydrochloride TABS
- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO
- Exkivity
- Firmagon INJ 120MG/VIAL, 80MG
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Folotyn
- Fotivda
- Fruzaqla
- Fulvestrant
- Gavreto
- Gefitinib
- Gilotrif
- Gomekli
- Ibrance
- Iclusig
- Idarubicin Hcl
- Idarubicin Hydrochloride
- Idhifa
- Imatinib Mesylate TABS
- Imbruvica CAPS
- Imbruvica SUSP
- Imbruvica TABS 280MG, 420MG, 560MG
- Imfinzi
- Inlyta
- Inqovi
- Itovebi
- Iwifin
- Jakafi
- Jaypirca
- Jevtana
- Keytruda INJ 100MG/4ML
- Kiskali

- KISQALI Femara 200 Dose
- KISQALI Femara 400 Dose
- KISQALI Femara 600 Dose
- KOSSELUGO
- KRAZATI
- KYPROLIS
- LAPATINIB DITOSYLATE
- LAZCLUZE
- LENALIDOMIDE
- LENVIMA 10 Mg Daily Dose
- LENVIMA 12mg Daily Dose
- LENVIMA 14 Mg Daily Dose
- LENVIMA 18 Mg Daily Dose
- LENVIMA 20 Mg Daily Dose
- LENVIMA 24 Mg Daily Dose
- LENVIMA 4 Mg Daily Dose
- LENVIMA 8 Mg Daily Dose
- LIBTAYO
- LONSURF
- LORBRENA
- LUMAKRAS
- LUMOXITI
- LYNPARZA TABS
- LYTGABI
- MEKINIST
- MEKTOVI
- MELPHALAN Hydrochloride
- MITOMYCIN INJ 20MG, 40MG, 5MG
- MUTAMYCIN
- MYLOTARG
- NELARABINE
- NILOTINIB Hydrochloride
- NINLARO
- NIPENT
- NUBEQA
- ODOMZO
- OGSIVEO
- OJEMDA
- OJJAARA
- ONUREG
- OPDIVO INJ 100MG/10ML,  
240MG/24ML, 40MG/4ML
- ORSERDU

- Oxaliplatin INJ 100MG, 100MG/20ML
- Paclitaxel Protein-bound Particles INJ 900MG; 100MG
- Pazopanib Hydrochloride
- Pemazyre
- Pemetrexed INJ 100MG, 500MG
- Pemetrexed Disodium
- Perjeta
- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose
- Pomalyst
- Proleukin
- Qinlock
- Retevmo
- Revlimid
- Revuforj
- Rezlidhia
- Romidepsin INJ 10MG
- Romvimza
- Rozlytrek CAPS
- Rubraca
- Rydapt
- Scemblix
- Sorafenib
- Sorafenib Tosylate TABS
- Stivarga
- Sunitinib Malate
- Synribo
- Tabrecta
- Tafenlar
- Tagrisso
- Talzenna
- Tassigna
- Tazverik
- Tecentriq
- Tecentriq Hybreza
- Temsirolimus
- Tepmetko
- Tevimbra
- Thiotepa INJ 15MG
- Tibsovo
- Toremifene Citrate

- Trelstar Mixject
- Tretinoin CAPS
- Truqap
- Truseltiq
- Tukysa
- Turalio
- Valchlor
- Vanflyta
- Vectibix INJ 100MG/5ML
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Vitrakvi
- Vizimpro
- Vonjo
- Voranigo
- Vyxeos
- Welireg
- Xalkori
- Xospata
- Xpovio
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly
- Xtandi
- Yervoy
- Yondelis
- Yonsa
- Zaltrap
- Zanosar
- Zejula
- Zelboraf
- Zolinza
- Zydelig
- Zykadia TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medical record documentation of the diagnosis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an oncologist or in certain conditions a hematologist, endocrinologist or neurologist. For chronic graft versus host disease, a transplant specialist. For systemic mast cell disease, an allergist or immunologist.
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Drug must be prescribed for a FDA approved indication. If prescribed for non-cancer indication that is not FDA approved, the off-label use of the drug must be for a medically accepted indication that is supported by AHFS (American Hospital Formulary Service) Drug Information or Micromedex DrugDex. If prescribed for a cancer indication that is not FDA approved, the off-label use of the drug must be supported by NCCN (National Comprehensive Cancer Network) guidelines, AHFS (American Hospital Formulary Service) Drug Information, Micromedex DrugDex, Clinical Pharmacology, Lexi-Drugs, or research found in peer reviewed medical literature in accordance with Chapter 15 of the Medicare Benefit Policy Manual.

# CAPLYTA

## Products Affected

- Caplyta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: For treatment of schizophrenia: failure of two of the following: Latuda, Rexulti (requires PA for new starts), Vraylar (requires step therapy for new starts), Fanapt (requires step therapy for new starts). For treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression): failure of two of the following: lithium, divalproex sodium, Latuda, quetiapine or olanzapine.

# CARBAGLU

## Products Affected

- Carglumic Acid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	A) For hyperammonemia type III, Initial: 1) Diagnosis confirmed by DNA testing and 2) Objective, measurable treatment goals are provided. B) For hyperammonemia due to propionic acidemia or methylmalonic acidemia, Initial: medical record documentation of the diagnosis. Renewal for all indications: Medical record documentation of stabilization of disease progression such as stabilization of neurologic impairments or seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	N/A

# CAYSTON

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## Products Affected

- Cayston

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of 1) FEV1 between 25% and 90% predicted and 2) Pseudomonas aeruginosa infection.
Age Restrictions	Age at least 7 years
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Documentation of failure of or resistance to tobramycin (TOBI).

# CERDELGA

## Products Affected

- Cerdelga

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Diagnostic confirmation by one of the following: a) biochemical assay showing decreased glucocerebrosidase activity in white blood cells or skin fibroblasts or b) genotyping revealing 2 pathogenic mutations of the glucocerebrosidase gene, and 2) Signs and symptoms that are severe enough to result in one or more of the following conditions: moderate-to-severe anemia, thrombocytopenia with bleeding tendency, bone disease, or significant hepatomegaly or splenomegaly, and 3) Documentation from a FDA-cleared test that the patient is an extensive, intermediate or poor CYP2D6 metabolizer and 4) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization of disease progression, such as 1) Improvement in hematologic markers, such as increased hemoglobin, hematocrit, or platelet counts or 2) Reduction in spleen or liver volume, or biochemical markers, such as chitotrisidase, ACE, acid phosphatase tartrate resistant (TRAP), or skeletal markers, such as DEXA scan, bone pain, bone age (for patient age 14 years or less).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	For CYP2D6 extensive and intermediate metabolizers, the dose should not exceed 84mg twice daily. For CYP2D6 poor metabolizers, the dose should not exceed 84mg daily.

# CEREZYME

## Products Affected

- Cerezyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Diagnostic confirmation by one of the following: a) biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts is less than or equal to 30% of normal activity or b) genotyping revealing 2 pathogenic mutations of the glucocerebrosidase gene, and 2) Signs and symptoms that are severe enough to result in one or more of the following conditions: moderate-to-severe anemia, thrombocytopenia with bleeding tendency, bone disease, or significant hepatomegaly or splenomegaly, and 3) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization of disease progression, such as 1) Improvement in hematologic markers, such as increased Hgb/Hct and/or platelet counts or 2) Reduction in spleen or liver volume, or biochemical markers, such as chitotrisidase, ACE, acid phosphatase tartrate resistant (TRAP), or skeletal markers, such as DEXA scan, bone pain, bone age (for patient age 14 years or less).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label. Dose range: 2.5/kg IV 3 times weekly to 60 units/kg IV every 2 weeks. Usual dosage is 60 units/kg IV every 2 weeks.

# CHENODAL

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## Products Affected

- Chenodal

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation that the patient is not a candidate for laparoscopic cholecystectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Failure of ursodiol.

# CHOLBAM

## Products Affected

- Cholbam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Bile acid synthesis defect, initial: medical record documentation of a bile acid synthesis disorder. First renewal after 4 months of initiating treatment: medical record documentation of liver function improvement and lack of complete biliary obstruction. Ongoing renewal criteria: lack of complete biliary obstruction. 2) Peroxisomal disorders, initial: Medical record documentation that Cholbam will be used adjunctively, and that there are liver disease manifestations, steatorrhea, or complications due to decreased absorption of fat soluble vitamins. First renewal after 4 months of initiating treatment: medical record documentation of liver function improvement and lack of complete biliary obstruction. Ongoing renewal criteria: lack of complete biliary obstruction.
Age Restrictions	N/A
Prescriber Restrictions	Hepatologist or gastroenterologist
Coverage Duration	Initial: 4 months. Renewal: 12 months.
Other Criteria	N/A

# CIMZIA

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## Products Affected

- Cimzia
- Cimzia Starter Kit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Rheumatoid arthritis (RA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 2) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 3) Plaque psoriasis (PsO) initial: involvement of at least 3% of body surface area or hand, foot, face, scalp or genital involvement. PsO renewal: improvement in affected BSA, plaque severity and/or functioning. 4) Ankylosing spondylitis (AS) renewal: improved functioning and/or signs and symptoms of AS. 5) Crohn's Disease (CD) renewal: medical record documentation of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. 6) Active non-radiographic axial spondyloarthritis renewal: improved functioning and/or signs and symptoms of active non-radiographic axial spondyloarthritis. 7) polyarticular juvenile idiopathic arthritis (pJIA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Plaque psoriasis: dermatologist. PsA: dermatologist or rheumatologist. RA, pJIA, Ankylosing spondylitis, and nonradiographic spondyloarthritis: rheumatologist. Crohn's disease: gastroenterologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	RA initial: Failure of or contraindication to two of the following: adalimumab (Humira or adalimumab-adbm), Enbrel, Simponi, Actemra, Orencia, Rinvoq, or Xeljanz (IR or XR). All require prior authorization. PsO initial: Failure of or contraindication to two of the following: adalimumab (Humira or adalimumab-adbm), Enbrel, Otezla, Cosentyx, Skyrizi, Stelara. PsA initial: Failure of or contraindication to two of the following: adalimumab (Humira or adalimumab-adbm), Enbrel, Simponi, Orencia, Otezla, Cosentyx, Skyrizi, Stelara, Rinvoq, or Xeljanz (IR or XR). AS initial: Failure of or contraindication to two of the following: adalimumab (Humira or adalimumab-adbm), Enbrel, Simponi, Cosentyx, or Xeljanz (IR or XR). All have prior authorization. CD initial: Failure of

	adalimumab (Humira or adalimumab-adbm) and Stelara with prior authorization. Active non-radiographic axial spondyloarthritis initial: failure of one non-steroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac.
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# CINRYZE

## Products Affected

- Cinryze

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Documentation of hereditary angioedema Type I and II confirmed by genetic testing, or complement studies of C4, C1INH antigenic and C1INH functional levels supporting the diagnosis. For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history. Renewal criteria for long term prevention: Documentation of a reduction in the number of angioedema attacks, improvement in the severity and duration of attacks or clinical documentation of functional improvement
Age Restrictions	Age at least 6 years.
Prescriber Restrictions	Hematologist, allergist or immunologist
Coverage Duration	Short term prevention: 1 procedure. Long term prevention initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

## CITALOPRAM 40MG

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### Products Affected

- Citalopram Hydrobromide TABS 40MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Not covered for members age 60 years and older who newly start on citalopram and using more than 20mg of citalopram per day.
Required Medical Information	N/A
Age Restrictions	Prior Authorization applies to members who newly start on citalopram and are 60 years or older.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# CLOBAZAM

## Products Affected

- Clobazam SUSP 2.5MG/ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age at least two.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: documentation of an inability to swallow solid dosage forms.

# COBENFY

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## Products Affected

- Cobenfy
- Cobenfy Starter Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of schizophrenia.
Age Restrictions	Age of at least 18 years
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug. Failure of two of the following: lurasidone, aripiprazole, risperidone, olanzapine, quetiapine, ziprasidone.

# COLONY STIMULATING FACTORS

## Products Affected

- Fulphila
- Fylnetra
- Granix
- Leukine INJ 250MCG
- Neulasta
- Nyvepria
- Rolvedon
- Stimufend
- Udenyca
- Udenyca Onbody
- Zarxio
- Ziextenzo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	1) AIDS Neutropenia (Leukine) and 2) Myelodysplastic Syndromes (Leukine)
Exclusion Criteria	N/A
Required Medical Information	Documentation of one the following: a) receiving myelosuppressive chemotherapy for a non-myeloid malignancy, receiving chemotherapy for AML, post-induction chemotherapy for AML (Leukine only), or acute exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) (for Neulasta and Leukine only), or b) BMT (allogeneic or autologous) or c) autologous peripheral blood progenitor cell (PBPC) transplant or d) severe chronic neutropenia and not on interferon-ribavirin based Hepatitis C treatment or e) AIDS or f) myelodysplastic syndromes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

# CORLANOR

## Products Affected

- Corlanor SOLN
- Ivabradine Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Adults with chronic heart failure: medical record documentation of the following: 1) Ejection fraction of 35% or less and 2) In sinus rhythm with a resting heart rate of at least 70 beats per minute.
Age Restrictions	Stable symptomatic heart failure due to dilated cardiomyopathy (DCM): at least 6 months of age to less than 19 years of age.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	1) Receiving maximally tolerated doses of a beta blocker or there is a medical reason why a beta blocker cannot be used and 2) failure of a) an angiotensin receptor enzyme inhibitor or angiotensin receptor blocker or b) a mineralcorticoid receptor antagonist. 3) For oral solution only: Documentation of an inability to swallow solid dosage forms.

# COSENTYX

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## Products Affected

- Cosentyx INJ 125MG/5ML, 150MG/ML
- Cosentyx Sensoready Pen
- Cosentyx Unoready

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Plaque psoriasis (PsO) initial: involvement of at least 3% of body surface area or hand, foot, face, scalp, or genital involvement. PsO renewal: improvement in affected body surface area, plaque severity and/or functioning. 2) Psoriatic arthritis renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 3) Ankylosing spondylitis renewal: improved functioning and/or signs and symptoms of AS. 4) Active non-radiographic axial spondyloarthritis renewal: improved functioning and/or signs and symptoms of active non-radiographic axial spondyloarthritis. 5) Enthesitis-related arthritis (ERA) renewal: improved functioning and/or signs and symptoms of ERA. 6) Hidradenitis suppurativa (HS): initial: moderate to severe disease evident by documentation of Hurley Stage II or III and at least 3 abscesses or inflammatory nodules. HS renewal: reduction in nodules and abscesses.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Plaque psoriasis and hidradenitis suppurativa: dermatologist. Psoriatic arthritis: dermatologist or rheumatologist. Ankylosing spondylitis, nonradiographic spondyloarthritis, enthesitis-related arthritis: rheumatologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	PsO initial: failure of 1) one topical agent such as a corticosteroid (i.e. betamethasone or clobetasol), calcipotriene, tazarotene (requires prior authorization), or tacrolimus and 2) methotrexate or cyclosporine. Ankylosing spondylitis, active non-radiographic axial spondyloarthritis and active enthesitis-related arthritis, initial: failure of one non-steroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac.

# CRENESSITY

## Products Affected

- Crenessity CAPS 100MG, 50MG
- Crenessity SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Medical record and lab result confirmation of a diagnosis of classic congenital adrenal hyperplasia caused by 21-hydroxylase deficiency. 2) Documentation that Crenessity will be used in combination with supraphysiologic glucocorticoid replacement. Renewal: Documentation of a reduction in daily glucocorticoid replacement dose.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	For oral solution only: documentation of an inability to swallow solid oral dosage forms.

# CRESEMBA

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## Products Affected

- Cresemba CAPS 186MG
- Cresemba INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	For the treatment of invasive aspergillosis (not required for invasive mucormycosis): failure of voriconazole.

# CUVRIOR

## Products Affected

- Cuvrior

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Medical record documentation of stable Wilson's disease who are de-coppered and tolerant to penicillamine. 2) Renewal: medical record documentation of clinical benefit from treatment with Cuvrior.
Age Restrictions	At least 18 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Initial: Failure of or contraindication to penicillamine.

# CYSTADANE

## Products Affected

- Betaine Anhydrous

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of diagnostic confirmation such as by measurement of plasma and urine homocysteine levels. Renewal: Medical record documentation of stabilization of disease, such as decrease in plasma and urine homocysteine levels, improvement in neurological and neuromuscular function.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# CYSTEAMINE

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## Products Affected

- Cystadrops
- Cystaran

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Medical record documentation of corneal cysteine crystal deposits. Renewal criteria: medical record documentation of a reduction in corneal crystal deposits.
Age Restrictions	N/A
Prescriber Restrictions	Doctor who specialize in genetic or metabolic disorders or ophthalmologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# DALFAMPRIDINE

## Products Affected

- Dalfampridine Er

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	History of seizure or moderate or severe renal impairment defined as creatinine clearance less than or equal to 50 mL/min.
Required Medical Information	Initial criteria: medical record documentation of 1) Diagnosis of multiple sclerosis, and 2) Prior to initiation of therapy, the patient must have a timed 25-foot walk time to establish a baseline to evaluate treatment response. Renewal criteria: 1) Medical record documentation of an improvement in the timed 25-foot walk time compared to baseline maximum walk speed.
Age Restrictions	Age at least 18 years.
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 months. Renewal: Lifetime.
Other Criteria	If indicated, must be receiving concurrent therapy with a disease modifying agent such as Avonex, Betaseron, Extavia, glatiramer, Rebif, fingolimod, or dimethyl fumarate.

# DAYBUE

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## Products Affected

- Daybue

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record confirmation of a diagnosis of Rett syndrome. Renewal: Medical record documentation of maintenance or improvement of symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a neurologist
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	N/A

# DEFLAZACORT

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## Products Affected

- Deflazacort

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: medical record documentation of genetic testing confirmation of Duchenne muscular dystrophy. Renewal criteria: documentation of a positive treatment response (e.g. pulmonary function, muscle strength, functional ability, walk tests)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a specialist in Duchenne Muscular Dystrophy or neuromuscular disorders.
Coverage Duration	12 months
Other Criteria	Failure of or adverse effects to prednisone.

# DENGVAXIA

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## Products Affected

- Dengvaxia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Medical record documentation of a laboratory confirmed previous dengue infection. 2) Documentation of residence in an endemic area.
Age Restrictions	Age between 9 and 16 years.
Prescriber Restrictions	N/A
Coverage Duration	3 doses over 6 months
Other Criteria	N/A

# DIACOMIT

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## Products Affected

- Diacomit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Medical record documentation of Dravet syndrome. 2) Documentation that Diacomit will be taken with clobazam.
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: failure of or contraindication to Epidiolex (requires prior authorization).

## DICLOFENAC 3% GEL

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### Products Affected

- Diclofenac Sodium GEL 3%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	90 days
Other Criteria	Failure of or contraindication to imiquimod and topical 5-fluorouracil.

# DICLOFENAC SODIUM SOLUTION

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## Products Affected

- Diclofenac Sodium EXTERNAL SOLN 1.5%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	1) Cancer-related pain
Exclusion Criteria	N/A
Required Medical Information	1) Cancer related pain, initial: medical record documentation of cancer-related pain. 2) Osteoarthritis of the knee, initial: medical record confirmation of osteoarthritis of the knee.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# DIFICID

## Products Affected

- Dificid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of an infection caused by clostridium difficile.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	10 days
Other Criteria	Failure of or intolerance to vancomycin. For oral powder for suspension only: documentation of an inability to swallow oral dosage forms.

# DOJOLVI

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## Products Affected

- Dojolvi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD). Renewal: Documentation of improved muscle function, exercise tolerance, or health related quality of life.
Age Restrictions	N/A
Prescriber Restrictions	Genetic specialist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# DOPTELET

## Products Affected

- Doptelet

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Chronic immune thrombocytopenia (ITP): Initial criteria: Medical record documentation of platelet count less 30,000 per mm3. Renewal criteria: Medical record documentation of maintenance of platelet counts between 30,000 per mm3 and 150,000 per mm3 or an increase in platelet counts from baseline with resolution of bleeding episodes. 2) Chronic liver disease with thrombocytopenia: Platelets less than 50k.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a gastroenterologist, hepatologist, a hematologist, or a surgeon.
Coverage Duration	ITP: Initial 6 weeks, Renewal 24 weeks. Chronic liver disease with thrombocytopenia: 5 days.
Other Criteria	Chronic immune thrombocytopenia: insufficient response to systemic corticosteroids and immunoglobulin replacement. Chronic liver disease with thrombocytopenia: Documentation of upcoming procedure.

# DRIZALMA

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## Products Affected

- Drizalma Sprinkle

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: documentation of an inability to swallow solid oral dosage forms.

# DRONABINOL

## Products Affected

- Dronabinol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	The following criteria only applies to the treatment of nausea and vomiting associated with cancer chemotherapy: 1) failure of at least one of the following antiemetics: dimenhydrinate, meclizine, metoclopramide, promethazine, or prochlorperazine and 2) ondansetron.

# DROXIDOPA

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## Products Affected

- Droxidopa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal criteria: medical record documentation of treatment response including decrease in lightheadedness, dizziness or falls.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# DUPIXENT

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## Products Affected

- Dupixent

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>1) Atopic dermatitis initial (AD): body surface area involvement = 10% at baseline. 2) AD renewal criteria: medical record documentation of a positive treatment response such as a reduction in body surface area involvement, improvement in itching, improvement in functional ability, reduction in the Investigator Global Assessment or Eczema Area and Severity Index from baseline. 3) Moderate to severe asthma, eosinophilic phenotype initial: eosinophil count greater than or equal to 150 cells/mcL. 4) Moderate to severe asthma, oral corticosteroid dependent initial: documentation that chronic oral steroid use is required for asthma control. 5) Moderate to severe asthma, renewal: reduction in oral steroid use or in asthma symptoms. 6) Chronic rhinosinusitis with nasal polyposis (CR) initial: medical record documentation that 1) the condition is inadequately controlled and 2) that Dupixent will be used as add-on therapy. 7) CR renewal: documentation of treatment response such as reduction in steroid use or need for surgery. 8) Eosinophilic esophagitis (EE) initial: a) medical record documentation of a diagnosis of eosinophilic esophagitis confirmed by symptoms related to esophageal dysfunction and biopsy showing eosinophil-predominant inflammation (such as a peak value of <math>\geq 15</math> eosinophils per high power field (HPF) or 60 eosinophils per mm<sup>2</sup>. b) weight of at least 15kg. 9) EE renewal: documentation of a clinical response, such as improvement in dysphagia or histologic remission. 10) Prurigo nodularis, renewal: documentation of a clinical response, such as an improvement in pruritis, a reduction in nodular lesions, or improvement in functioning. 10) eosinophilic type COPD initial: eosinophil count of at least 300 cells/mcL. Renewal: Improvement in symptoms or less exacerbations.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with a dermatologist, pulmonologist, allergist, ENT, otolaryngologist, or immunologist. For EE: Gastroenterologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.

<b>Other Criteria</b>	Atopic dermatitis: For patients 12 years of age or older: 1) failure of one of the following very high potency topical steroids: augmented betamethasone, clobetasol or halobetasol and 2) failure of tacrolimus ointment, OR documentation that topical prescription therapies are not appropriate or are contraindicated. Moderate to severe asthma, eosinophilic phenotype or oral corticosteroid dependent: trial and failure of an ICS+LABA combo such as fluticasone/vilanterol or fluticasone/salmeterol. Uncontrolled COPD, initial: exacerbations while on triple therapy with an ICS + LAMA + LABA combo such as Trelegy or Breztri.
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# DUVYZAT

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## Products Affected

- Duvyzat

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: a) genetic testing results confirming a diagnosis of Duchenne muscular dystrophy. b) medical record documentation of male gender. Renewal criteria: documentation of a positive treatment response (e.g. pulmonary function, muscle strength, functional ability, walk tests)
Age Restrictions	At least 6 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a specialist in Duchenne Muscular Dystrophy or neuromuscular disorders.
Coverage Duration	12 months
Other Criteria	N/A

# EGRIFTA

## Products Affected

- Egrifta Sv

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, or head irradiation or trauma, 2) malignancy, active (either newly diagnosed or recurrent), malignancies should be inactive and completely treated prior to initiating therapy, 3) Pregnancy, 4) Body mass index less than or equal to 20 kg/m <sup>2</sup> . 5) Not approved for use in patients without HIV infection.
Required Medical Information	Initial criteria: 1) Lipodystrophy defined as a) For men: a waist circumference of greater than or equal to 95 cm or 37.5 inches or a waist-to-hip ratio of greater than or equal to 0.94 and b) For women: a waist circumference of greater than or equal to 94 cm or 37 inches or a waist-to-hip ratio of greater than or equal to 0.88. 2) Currently on anti-retroviral therapy. Renewal criteria: documentation of treatment response such as reduction in visceral adipose tissue as demonstrated from waist circumference or CT scan.
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist or HIV specialist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# ELAPRASE

## Products Affected

- Elaprase

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Diagnostic confirmation of by such as presence of glycosaminoglycans (GAG) in the urine, deficiency in iduronate-2-sulfatase enzyme activity, or genetic testing, and 2) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization of disease progression, such as improvement in percent predicted FVC, improvement in 6-minute walk test, reduction in urinary GAG levels, or reduction in liver or spleen size.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label: 0.5mg/kg IV once weekly.

# ELMIRON

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## Products Affected

- Elmiron

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Hemorrhagic cystitis
Exclusion Criteria	N/A
Required Medical Information	Renewal criteria: medical record documentation of an improvement in symptoms such as a reduction in bladder pain.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	N/A

# EMEND

## Products Affected

- Aprepitant CAPS
- Emend SUSR

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concomitant use of pimozide.
Required Medical Information	Confirmation of diagnosis and use as prophylaxis and not for established nausea and vomiting.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PONV: one dose. Chemotherapy: 12 months.
Other Criteria	Chemotherapy: 1) Requires concurrent treatment with IV or oral Zofran (ondansetron) or Kytril (granisetron) or Aloxi (palonosetron) and dexamethasone. 2) Part B versus D determination will be made to determine coverage.

# EMGALITY

## Products Affected

- Emgality

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Episodic cluster headache: 1) Initial: medical record documentation of the diagnosis and that the patient has experienced at least 2 cluster periods from 7 to 365 days, separated by pain free periods lasting at least 3 months. 2) Renewal: documentation of treatment response including a reduction in headaches, decreased abortive medication use, or emergency room visits. 3) Not used in combination with another CGRP inhibitor. Migraines: 1) Initial: episodic migraine, 4-14 headache days per month. Chronic migraines, 15 or more headache days per month with at least 8 days of migraines for 3 months. 2) Renewal: documentation of treatment response including decrease in the number of migraine days, less migraine episodes, decreased abortive medication usage, or emergency room visits related to migraine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	1) Episodic Migraine prophylaxis and chronic migraine prophylaxis: failure of propranolol and topiramate.

# EMSAM

## Products Affected

- Emsam

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Concomitant use of the any of the following medications: SSRIs, SNRIs, TCAs, MAOIs, sympathomimetic amines including amphetamines, meperidine, tramadol, methadone, mirtazapine, bupropion, cyclobenzaprine, carbamazepine and oxcarbamazepine.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Failure of or intolerance to at least 2 of the following: 1) a selective serotonin receptor reuptake inhibitor such as citalopram, escitalopram, fluoxetine, paroxetine, or sertraline, 2) an SNRI such as venlafaxine or duloxetine, 3) bupropion or 4) mirtazapine.

# ENBREL

## Products Affected

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Rheumatoid arthritis (RA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 2) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 3) Ankylosing spondylitis (AS) Renewal: Improved functioning and/or symptoms. 4) Plaque psoriasis (PsO initial: involvement of more than 3% of body surface area or hand, foot, face, scalp or genital involvement. PsO renewal: improvement in affected BSA, plaque severity and/or functioning. 5) Juvenile idiopathic arthritis (JIA) and juvenile psoriatic arthritis (JPsA) renewal: Improved functioning and/or improvement in tender joint count and swollen joint count.
Age Restrictions	N/A
Prescriber Restrictions	Rheumatoid arthritis, ankylosing spondylitis, juvenile idiopathic arthritis and juvenile psoriatic arthritis: rheumatologist. Plaque psoriasis: dermatologist. Psoriatic arthritis : rheumatologist or dermatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	RA Initial: failure of methotrexate and at least one other DMARD such as leflunomide, sulfasalazine, or hydroxychloroquine. AS initial: failure of one oral non-steroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac. PsO initial: Failure of 1) one topical agent such as a corticosteroid (i.e. betamethasone or clobetasol), calcipotriene, tazarotene (requires prior authorization), or tacrolimus and 2) methotrexate or cyclosporine. JIA and JPsA initial: failure of methotrexate for at least 8 weeks.

# ENDARI

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## Products Affected

- L-glutamine PACK

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal criteria: medical record documentation that the drug has been effective in reducing the number of sickle cell crisis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Medical record documentation of failure of or intolerance to hydroxyurea. Failure defined as continued acute complications or pain crisis or continued need for blood transfusions while on hydroxyurea.

# ENSPRYNG

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## Products Affected

- Enspryng

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder
Age Restrictions	N/A
Prescriber Restrictions	Neurologist or ophthalmologist
Coverage Duration	12 months
Other Criteria	N/A

# ENTYVIO

## Products Affected

- Entyvio Pen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Ulcerative Colitis (UC) renewal: medical record documentation of treatment response such as decrease in bloody stools per day, elimination of signs of toxicity, or clinical remission. Crohn's disease (CD) renewal: a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a gastroenterologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	UC Initial: Failure of two of the following: adalimumab (Humira or adalimumab-adbm), Stelara, Rinvoq, Simponi and Xeljanz. All require prior authorization. CD initial: Failure of two of the following: adalimumab (Humira or adalimumab-adbm), Stelara, Rinvoq, and Simponi. All require prior authorization.

# EOHILIA

## Products Affected

- Eohilia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: medical record documentation of a diagnosis of eosinophilic esophagitis confirmed by symptoms related to esophageal dysfunction and biopsy showing eosinophil-predominant inflammation (such as a peak value of $f \geq 15$ eosinophils per high power field (HPF) or 60 eosinophils per mm <sup>2</sup> . Renewal: documentation of a clinical response, such as improvement in dysphagia or histologic remission.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# EPIDIOLEX

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## Products Affected

- Epidiolex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: 1) For all diagnoses: Epidiolix must be used as adjunctive treatment. 2) For Lennox-Gastaut Syndrome: failure of two of the following: clonazepam, valproate, topiramate, lamotrigine, felbamate or rufinamide.

# EPRONTIA

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## Products Affected

- Eprontia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to new starts only. Initial: Documentation of an inability to swallow oral dosage forms or contents of sprinkle capsules.

## ERYTHROPOIESIS-STIMULATING AGENTS

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### Products Affected

- Aranesp Albumin Free INJ  
100MCG/0.5ML, 100MCG/ML,  
10MCG/0.4ML, 150MCG/0.3ML,  
200MCG/0.4ML, 200MCG/ML,  
25MCG/0.42ML, 25MCG/ML,  
300MCG/0.6ML, 40MCG/0.4ML,  
40MCG/ML, 500MCG/ML,  
60MCG/0.3ML, 60MCG/ML
- Procrit
- Retacrit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Anemia associated with chronic kidney disease (CKD): a) Hgb below 10 g/dL or Hct below 30% and b) ferritin at least 100 ng/mL and/or c) transferrin saturation at least 20%. 2) Anemia associated with cancer treatment for non-myeloid cancers: a) Hgb below 10 g/dL or Hct below 30% and b) ferritin at least 100 ng/mL and/or c) transferrin saturation at least 20%. 3) Anemia associated with Zidovudine therapy in HIV/AIDS: a) Hgb below 10 g/dL or Hct below 30% and b) transferrin saturation at least 20%, and c) endogenous erythropoietin below 500 IU/L, 4) Surgery: a) high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery and b) baseline Hgb greater than 10g/dL, but below 13g/dL. Renewal criteria for 1-3: transferrin saturation greater than 20%.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CKD and HIV: 12 months. Cancer: 6 months. Surgery: 1 month.
<b>Other Criteria</b>	1) Anemia associated with zidovudine therapy: zidovudine dose less than 4200mg per week verified by claim history. 2) For end stage renal disease (ESRD) patients on dialysis, Part B versus Part D determination will be made to determine if the drug prescribed will be used for an ESRD-related condition. For ESRD-related conditions, the drug will be covered under Part B and provided by the dialysis center.

# EVENTITY

## Products Affected

- Eventity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Stroke or myocardial infarction in the last 12 months. 2) Uncorrected hypocalcemia.
Required Medical Information	Medical record documentation of high risk or very high risk of fracture defined as a history of osteoporotic fracture, or multiple risk factors for fracture (such as bone mineral density less than -2.5, previous minimal trauma fracture as an adult, low weight or body mass index, history of hip fracture in a first degree relative, tall stature or use of tobacco), or failure of other available osteoporosis therapy. Very high risk of fracture is defined as recent fracture (within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm such as long term steroids, very low T-score such as less than -3, high risk of falls or history of injurious falls, and very high fracture probability determined by the Fracture Risk Assessment Tool (FRAX).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months maximum. Use is not recommended for longer.
Other Criteria	Failure of or contraindication to 1) oral bisphosphonates and 2) Prolia. These criteria do not apply if considered very high risk for fracture.

# EVRYSDI

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## Products Affected

- Evrysdi SOLR

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record confirmation of a diagnosis of spinal muscle atrophy (SMA) confirmed by genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	12 months
Other Criteria	N/A

# EXENATIDE

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## Products Affected

- Bydureon Bcise
- Byetta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of type 2 diabetes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# EXONDYS

## Products Affected

- Exondys 51

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Medical record documentation of a confirmed mutation of the Duchenne muscular dystrophy (DMD) gene that is amenable to exon 51 skipping. Renewal criteria: Documentation of an improvement in symptoms including distance that a patient can walk on a flat, hard surface in a period of 6 minutes and/or reduction in disease progression.
Age Restrictions	N/A
Prescriber Restrictions	Neurologist or in consultation with a neurologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# FABHALTA

## Products Affected

- Fabhalta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Paroxysmal nocturnal hemoglobinuria (PNH): medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria. PNH Renewal: medical record documentation of clinical benefit, such as increase in hemoglobin level from baseline. 2) Primary immunoglobulin A nephropathy (IgAN) initial: a) biopsy results confirming IgAN. b) laboratory results confirming proteinuria.
Age Restrictions	N/A
Prescriber Restrictions	PNH: Prescribed by, or in consultation with a hematologist or an oncologist. IgAN: Prescribed by, or in consultation with a nephrologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	IgAN: documentation of failure of or contraindication to Filspari (requires prior authorization).

# FABRAZYME

## Products Affected

- Fabrazyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) For males, diagnostic confirmation of a-galactosidase levels (a- GAL) of less than 1.5 nmol/hr/ml on plasma or less than 4nmol/hr/mg in leukocytes. For females, diagnostic confirmation based on low leukocyte a- GAL A or family history of genetic mutation analysis of the a- GAL A gene or characteristic findings e.g., angiokeratomas, telangiectasias, severe neuropathic pain and organ involvement, and 2) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization or slowing of disease progression.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label: 1 mg/kg IV infusion every 2 weeks.

# FASENRA

## Products Affected

- Fasenra
- Fasenra Pen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Asthma initial criteria: 1) Medical record documentation of a diagnosis of severe asthma with eosinophilic phenotype and 2) Blood eosinophil levels greater than or equal to 150 cells/mcL in the last 4 weeks. Asthma renewal criteria: documentation of or claims history showing a reduction in the use of oral steroids or reduction in asthma symptoms. Eosinophilic granulomatosis with polyangiitis (EGPA) initial: 1) diagnosis confirmed by documentation of asthma, and 2) blood eosinophil level of 10% or an absolute count of greater than 1000 cells/mm3. EGPA renewal criteria: documentation of response to treatment such as achievement of remission, decrease in the use of steroids, decrease in the rate of relapses or improvement in asthma symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Asthma: Prescribed by or in consultation with a pulmonologist, allergist, or immunologist. EGPA: prescribed by or in consultation with a rheumatologist, pulmonologist, immunologist or vasculitis specialist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Asthma, initial: failure of an inhaled corticosteroid and a long-acting beta agonist.

# FETZIMA

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## Products Affected

- Fetzima
- Fetzima Titration Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Failure of 1) an SSRI such as sertraline or fluoxetine and 2) an SNRI such as venlafaxine and or duloxetine.

# FILSPARI

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## Products Affected

- Filspari

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Immunoglobulin A nephropathy initial: 1) medical record documentation of biopsy confirmed primary immunoglobulin A nephropathy. Renewal: medical record documentation of a decrease in urine protein-to-creatinine ratio from baseline.
Age Restrictions	Age of at least 18 years
Prescriber Restrictions	Prescribed by, or in consultation with a nephrologist
Coverage Duration	Initial: 6 months. Renewal: Lifetime
Other Criteria	N/A

# FILSUEZ

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## Products Affected

- Filsuvez

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of genetic testing confirmation of junctional epidermolysis bullosa (JEB) or dystrophic epidermolysis bullosa (DEB). Renewal: medical record documentation of clinical response (i.e. wound healing).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist.
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	N/A

# FINGOLIMOD

## Products Affected

- Fingolimod Hydrochloride
- Gilenya CAPS 0.25MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Unstable angina, transient ischemic attack, myocardial infarction, stroke, heart failure Class III/IV or decompensated heart failure requiring hospitalization within the last 6 months. 2) Concomitant Class Ia or Class III anti-arrhythmic drugs. 3) Mobitz type II second-degree, third-degree atrioventricular block, sick-sinus syndrome unless the patient has a functional pacemaker. 4) QTc interval at baseline 500 milliseconds or greater.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Lifetime
Other Criteria	Documentation that fingolimod is being requested for monotherapy and is not intended to be used in combination with other disease modifying multiple sclerosis agents.

# FINTEPLA

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## Products Affected

- Fintepla

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Failure of or contraindication to Epidiolex (requires PA for new starts).

# FIRDAPSE

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## Products Affected

- Firdapse

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	History of seizure
Required Medical Information	Initial: Confirmation of a diagnosis of Lambert-Eaton myasthenic syndrome via EMG or antibody testing. Renewal: Documentation of a treatment response such as a reduction in muscle weakness or functional impairment.
Age Restrictions	Age at least 6 years.
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# FYCOMPA

## Products Affected

- Fycompa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: For tablets and suspension: 1) For the treatment of partial-onset seizures: failure of two of the following: carbamazepine, oxcarbazepine, lacosamide, phenytoin, topiramate, divalproex, felbamate, tiagabine, lamotrigine, gabapentin, zonisamide, and levetiracetam. 2) For the treatment of primary generalized tonic-clonic seizures: failure of two of the following topiramate, lacosamide, lamotrigine, phenytoin, and levetiracetam. For suspension only: inability to swallow oral dosage forms.

# GALAFOLD

## Products Affected

- Galafold

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) For males, diagnostic confirmation of a-galactosidase levels (a- GAL) of less than 1.5 nmol/hr/ml on plasma or less than 4nmol/hr/mg in leukocytes. For females, diagnostic confirmation based on low leukocyte a- GAL A or family history of genetic mutation analysis of the a- GAL A gene or characteristic findings e.g., angiokeratomas, telangiectasias, severe neuropathic pain and organ involvement, and 2) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization or slowing of disease progression.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# GARDASIL

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## Products Affected

- Gardasil 9 INJ 0.5ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age 9-45 years
Prescriber Restrictions	N/A
Coverage Duration	Series of 3 doses in 12 months.
Other Criteria	N/A

# GATTEX

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## Products Affected

- Gattex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Medical record documentation that the patient is dependent on parenteral support. Renewal criteria: Medical record documentation of a decrease in parenteral support such as a decrease in volume and/or frequency.
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist or GI specialist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# GEMTESA

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## Products Affected

- Gemtesa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: for overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH), documentation that the member is receiving pharmacological therapy for BPH.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria does not apply to adult males with BPH: Failure of mirabegron.

# GRANISETRON

## Products Affected

- Granisetron Hcl INJ 1MG/ML
- Granisetron Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prevention or treatment of nausea and vomiting associated with cancer chemotherapy or radiation: documentation of current treatment with 1) moderately or highly emetogenic chemotherapy or 2) total body, upper hemi-body or abdominal irradiation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Nausea and vomiting, cancer treatment: 12 months. Post-operative nausea and vomiting: one dose.
Other Criteria	1) Not receiving concurrent oral or IV Zofran, Kytril, Anzemet or Emend. 2) If granisetron is being used as part of a cancer chemotherapy regimen, Part B versus D determination will be made to determine coverage.

# HAEGARDA

## Products Affected

- Haegarda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Documentation of hereditary angioedema Type 1 and II confirmed by genetic testing or complement studies of C4, C1INH antigenic and C1INH functional levels supporting the diagnosis. 2) For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history. Renewal criteria for long term prevention: Documentation of a reduction in the number of angioedema attacks, improvement in the severity and duration of attacks or clinical documentation of functional improvement.
Age Restrictions	N/A
Prescriber Restrictions	Prescribing restricted to or in consultation with a hematologist, allergist or an immunologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# HETLIOZ

## Products Affected

- Hetlloz Lq
- Tasimelteon

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	A) Non-24 hour sleep-wake cycle, initial: documentation of a diagnosis that meets the International Classification of Sleep Disorders diagnostic criteria. Renewal: documentation of an increase in nighttime sleeping and decrease in daytime napping. B) Dyssomnia due to Smith-Magenis syndrome, initial: medical record documentation of the diagnosis. Renewal: documentation of an improvement in sleep quality.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# HYFTOR

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## Products Affected

- Hyftor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: medical record documentation of a confirmation of facial angiofibroma associated with tuberous sclerosis. Renewal: medical record documentation of a clinical response to therapy, such as improvement in size or redness of facial angiofibroma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 12 weeks. Renewal: 12 months.
Other Criteria	N/A

# ICATIBANT

## Products Affected

- Icatibant Acetate
- Sajazir

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Documentation of hereditary angioedema Type 1 and II confirmed by genetic testing or complement studies of C4, C1INH antigenic and C1INH functional levels supporting the diagnosis. For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history. Renewal criteria for long-term prevention: Documentation of a reduction in symptoms such as abdominal pain, cutaneous pain and cutaneous swelling.
Age Restrictions	Age at least 18 years.
Prescriber Restrictions	Hematologist, allergist or immunologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# IMKELDI

## Products Affected

- Imkeldi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Medical record documentation of the diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an oncologist, or in certain conditions a hematologist, endocrinologist, neurologist, allergist or dermatologist.
Coverage Duration	Lifetime
Other Criteria	1) Documentation of an inability to swallow oral tablets. 2) Drug must be prescribed for an FDA approved indication, or if prescribed for non-cancer indication that is not FDA approved, the off-label use of the drug must be for a medically accepted indication that is supported by AHFS (American Hospital Formulary Service) Drug Information or Micromedex DrugDex, or if prescribed for a cancer indication that is not FDA approved, the off-label use of the drug must be supported by NCCN (National Comprehensive Cancer Network) guidelines, AHFS (American Hospital Formulary Service) Drug Information, Micromedex DrugDex, Clinical Pharmacology, Lexi-Drugs, or research found in peer reviewed medical literature in accordance with Chapter 15 of the Medicare Benefit Policy Manual.

# IMPAVIDO

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## Products Affected

- Impavido

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record confirmation of a diagnosis of leishmaniasis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an infectious disease specialist
Coverage Duration	28 days
Other Criteria	Failure of amphotericin B or Ambisome.

# INBRIJA

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## Products Affected

- Inbrija

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: Documentation that the patient's off time has been reduced with Inbrija.
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 month. Renewal: Lifetime.
Other Criteria	Initial: failure of maximum tolerable doses of oral levodopa/carbidopa and one of the following: selegiline, ropinirole, pramipexole, tolcapone and entacapone.

# INCRELEX

## Products Affected

- Increlex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Evidence of closure of epiphyseal plate. 2) Active or suspected neoplasia.
Required Medical Information	1) Primary IGF-1 Deficiency, Initial: a) Secondary causes have been ruled out, such as growth hormone deficiency, malnutrition, hypothyroidism, and chronic corticosteroid therapy, b) Height standard deviation score less than or equal to -3, c) basal IGF-1 standard deviation score of less than or equal to -3 and d) normal or elevated growth hormone, greater than or equal to 10ng/ml to at least two stimuli including insulin, levodopa, arginine, clonidine, or glucagon. Renewal criteria: documentation of clinical improvement, such as an increase in height velocity. 2) Growth Hormone Gene Deletion Initial: evidence of gene deletion and (+) neutralizing antibodies to growth hormone. Renewal criteria: documentation of clinical improvement, such as an increase in height velocity.
Age Restrictions	Age 2-18 years
Prescriber Restrictions	Endocrinologist
Coverage Duration	12 months
Other Criteria	N/A

## INFLIXIMAB

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### Products Affected

- Avsola
- Inflectra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	1) Moderate to severe heart failure, doses greater than 5mg/kg should not be administered
<b>Required Medical Information</b>	1) Crohn's disease (CD) renewal: a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. 2) Rheumatoid arthritis (RA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 3) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count. 4) Ankylosing spondylitis (AS) renewal: improved functioning and/or signs and symptoms of AS. 5) Juvenile idiopathic arthritis (JIA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count. 6) Plaque psoriasis (PsO) initial: involvement of more than 3% of body surface area or hand, foot, face, scalp or genital involvement. PsO renewal: improvement in affected BSA, plaque severity and/or functioning. 7) Ulcerative Colitis (UC) renewal: medical record documentation of treatment response such as decrease in bloody stools per day, elimination of signs of toxicity, or clinical remission. 8) Hidradenitis suppurativa (HS) initial: moderate to severe disease evident by documentation of Hurley Stage II or III and at least 3 abscesses or inflammatory nodules. HS renewal: medical record documentation of a reduction in nodules or abscesses. 9) Uveitis initial: documentation of non-infectious, intermediate, posterior or panuveitis. Renewal: documentation that treatment response is being monitored for the following development of new inflammatory chorioretinal and/or inflammatory retinal vascular lesions, anterior chamber cell grade or vitreous haze, or visual acuity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Plaque psoriasis: dermatologist. Psoriatic arthritis, ankylosing spondylitis, and rheumatoid arthritis: rheumatologist. Crohn's disease and ulcerative colitis: gastroenterologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	RA initial: failure of methotrexate and at least one other DMARD such as leflunomide, sulfasalazine, or hydroxychloroquine. AS initial: failure of one non-steroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac. JIA initial: failure of an 8 week trial of

	methotrexate. PsO Initial: failure of 1) one topical agent such as a corticosteroid (i.e. betamethasone or clobetasol), calcipotriene, tazarotene (requires prior authorization), or tacrolimus (requires prior authorization) and 2) methotrexate or cyclosporine.
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# INGREZZA

## Products Affected

- Ingrezza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Tardive dyskinesia, renewal: medical record documentation of treatment response such as a reduction in the Abnormal Involuntary Movement Scale (AIMS) score from baseline, improvement in involuntary movement, or improvement in functional ability. Chorea associated with Huntington's disease, renewal: medical record documentation of a clinical response such as improvement in chorea, ability to perform activities of daily living, reduction in falls, or increase in quality of life.
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, movement disorder specialist or a psychiatrist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# INREBIC

## Products Affected

- Inrebic

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of the diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with an oncologist or a hematologist.
Coverage Duration	Lifetime
Other Criteria	1) Failure of Jakafi or the prescriber must provide a medical reason why Jakafi cannot be used. 2) Drug must be prescribed for an FDA approved indication or a medically accepted indication that is supported by AHFS (American Hospital Formulary Service) Drug Information or Micromedex DrugDex if for non-cancer use, or supported by NCCN Compendium, Clinical Pharmacology, Lexi-Drugs, and acceptable medical journals for cancer indication.

# INTRAVENOUS IMMUNE GLOBULIN

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## Products Affected

- Atgam
- Bivigam INJ 10%, 5GM/50ML
- Flebogamma Dif INJ 10GM/100ML, 10GM/200ML, 2.5GM/50ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamastan
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML
- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Octagam INJ 10GM/100ML, 10GM/200ML, 1GM/20ML, 2.5GM/50ML, 20GM/200ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Privigen
- Thymoglobulin

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically accepted Indications.
<b>Off-Label Uses</b>	1) HIV, 2) Allogeneic bone marrow transplant (BMT), 3) Pregnancy-associated idiopathic thrombocytopenic purpura, 4) Myasthenia Gravis (MG), 5) Autoimmune Mucocutaneous Blistering Disease (AMBD), 6) Autoimmune Hemolytic Anemia, Warm Type (AHA-W), 7) Polymyositis and 8) Dermatomyositis
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Acute Idiopathic Thrombocytopenic Purpura: platelet less than 30,000 or need to increase platelet prior to major, invasive surgery. 2) Chronic ITP: duration of illness less than 6 months, no concurrent illness/disease explaining thrombocytopenia, platelets persistently below 20,000. 3) ITP in pregnancy: previous deliveries of children with autoimmune thrombocytopenia or platelets below 30,000 associated with bleeding before delivery, or platelets below 75,000 during the current pregnancy or history of splenectomy. 4) Chronic B-Cell Lymphocytic Leukemia with hypogammaglobulinemia: IgG below 600 and evidence of specific antibody deficiency and repeated bacterial infections. 5) HIV: CD4+ greater than 200/mm <sup>3</sup> , and clinically symptomatic. 6) BMT: hematologic neoplasm, seropositive for CMV prior to transplant, severe hypogammaglobulinemia defined as IgG less than 400 within the first 100 days post transplant, and seronegative donor. 7) Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) including Guillain-Barre Syndrome: Difficulty with venous access for plasmapheresis, or rapidly progressive form of disease with symptoms less than 2 weeks or deteriorating ability to ambulate, or deteriorating PFTs. 8) Autoimmune Mucocutaneous Blistering Disease (AMBD): Diagnosis of pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid or epidermolysis bullous acquisita. 9) Autoimmune Hemolytic Anemia, Warm Type: Predominance of IgG antibodies or comorbid hepatomegaly or hepatosplenomegaly. 10) Polymyositis and Dermatomyositis: associated with severe disability. 11) Acute Myasthenia Gravis (AMG): a) Myasthenic exacerbation defined by difficulty swallowing, acute respiratory failure, or major functional disability or b) presurgical treatment. 12) Multifocal motor neuropathy (For Gammagard only): medical record documentation of treatment response such as improvement in functional ability such as grip strength.
<b>Age Restrictions</b>	N/A

<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Acute ITP, ITP in pregnancy, HIV, BMT, AMBD, AMG, 3 months: All other diagnoses: Lifetime
<b>Other Criteria</b>	1) For primary immunodeficiencies only, IVIG may be covered in the home under Medicare Part B if coverage guidelines are met. 2) Chronic ITP requires failure of prednisone. 3) AMG requires failure of two of the following: pyridostigmine, prednisone, azathioprine, or methotrexate. 4) AMBD requires a) failure of prednisone and at least one of the following: methotrexate, azathioprine, cyclosporine or cyclophosphamide or b) evidence of rapid disease progression and urgent administration of IVIG is medically necessary. 5) Polymyositis and Dermatomyositis require failure of prednisone and at least one of the following: methotrexate, azathioprine, cyclosporine or cyclophosphamide.

# IQIRVO

## Products Affected

- Iqirvo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Confirmation of a diagnosis of primary biliary cholangitis. 2) documentation of an inadequate treatment response to ursodeoxycholic acid (UDCA), or documented contraindication to UDCA. Renewal: 1) documentation of reduction in alkaline phosphatase (ALP) from baseline. 2) Continued use of ursodeoxycholic acid (UDCA) unless there is documentation of intolerance.
Age Restrictions	Age of at least 18 years or older.
Prescriber Restrictions	Prescribed by, or in consultation with a gastroenterologist or hepatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# IRON CHELATOR

## Products Affected

- Deferasirox
- Deferiprone
- Ferriprox SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For chronic iron overload due to blood transfusions (deferiprone and deferasirox) Initial: documentation of elevated sodium ferritin levels. For non-transfusion-dependent thalassemia syndromes (deferasirox only) Initial: 1) liver iron concentrations at least 5 milligrams of iron per gram of liver dry weight and 2) serum ferritin greater than 300 mcg/L. For transfusional iron overload in patients with sickle cell disease or other anemias (deferiprone only), initial: documentation of elevated sodium ferritin levels. Renewal criteria for all indications: reduction in total body iron, evidenced by decreased ferritin levels.
Age Restrictions	N/A
Prescriber Restrictions	Hematologist
Coverage Duration	12 months
Other Criteria	For chronic iron overload due to blood transfusions, Initial: Failure of deferoxamine or reason why deferoxamine cannot be used.

# ISOTRETINOIN

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## Products Affected

- Accutane
- Amnesteem
- Claravis CAPS 10MG
- Isotretinoin CAPS 10MG, 20MG, 30MG, 40MG
- Myorisan
- Zenatane

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Females who are pregnant or who may become pregnant and are not using at least two forms of contraception.
Required Medical Information	Medical record documentation of negative pregnancy test and use of reliable methods of birth control in females of child-bearing age.
Age Restrictions	Age at least 12 years.
Prescriber Restrictions	Dermatologist
Coverage Duration	20 weeks
Other Criteria	Documentation of failure of at least a 4 week trial of a) one oral antibiotic (e.g., tetracycline, doxycycline, minocycline, or erythromycin) and b) topical tretinoin.

# JOENJA

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## Products Affected

- Joenja

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Medical record confirmation of a diagnosis of activated phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS). 2) Weight of at least 45kg or greater.
Age Restrictions	At least 12 years of age
Prescriber Restrictions	Prescribed by, or in consultation with an immunologist, hematologist, oncologist, allergist or geneticist.
Coverage Duration	Lifetime
Other Criteria	N/A

# JOURNAVX

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## Products Affected

- Journavx

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of moderate to severe acute pain and that treatment is intended to be 14 days or less.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	14 days
Other Criteria	Failure of or contraindication to 1) an NSAID, and 2) a short-acting opioid.

# JUXTAPID

## Products Affected

- Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: diagnosis of homozygous familial hypercholesterolemia. Renewal criteria: reduction in LDL-C.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Failure of or intolerance to: 1) ezetimibe and 2) rosuvastatin or atorvastatin.

# JYNARQUE

## Products Affected

- Jynarque
- Tolvaptan TBPk

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Evidence of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD) as defined by 1) a confirmed glomerular filtration rate (GFR) decline of at least 5 mL/min per year over 1 year and/or 2.5 mL/min per year over a period of 5 years or 2) a total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart, or 3) Mayo Classification 1C to 1E.
Age Restrictions	N/A
Prescriber Restrictions	Nephrologist
Coverage Duration	Lifetime
Other Criteria	N/A

# KALYDECO

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## Products Affected

- Kalydeco

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: medical record documentation of a diagnosis of cystic fibrosis with genetic confirmation of a mutation in the CFTR gene that is responsive to Kalydeco (ivacaftor). Renewal criteria: medical record documentation of treatment response such as an improvement in FEV1, reduction in pulmonary exacerbation, or improvement in respiratory symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# KERENDIA

## Products Affected

- Kerendia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) eGFR less than 25 mL/min/1.73m <sup>2</sup> or 2) serum potassium greater than 5 mEq/L.
Required Medical Information	Medical record documentation of 1) a diagnosis of chronic kidney disease associated with type 2 diabetes and 2) eGFR of at least 25 mL/min/1.73m <sup>2</sup> .
Age Restrictions	Age at least 18 years
Prescriber Restrictions	Prescribed by, or in consultation with a nephrologist or a cardiologist
Coverage Duration	Lifetime
Other Criteria	N/A

# KEVEYIS

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## Products Affected

- Dichlorphenamide

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal criteria: medical record documentation of a reduction in the number, frequency or duration of paralytic attacks.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# KINERET

## Products Affected

- Kineret

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Rheumatoid Arthritis (RA) Renewal: Improved functioning and/or improvement in tender joint count and swollen joint count. 2) Neonatal onset multi-system inflammatory disease, renewal: improvement in symptoms or laboratory markers. 3) Deficiency of Interleukin-1 Receptor Antagonist (DIRA) renewal: documentation of a positive clinical response, such as low disease activity, or improvement in signs and symptoms.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA: Prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	RA Initial: 6 mo. Renewal: 12 mo. Neonatal Onset Multi-system Inflammatory Disease, DIRA: 12 mo.
<b>Other Criteria</b>	RA initial: failure of two of the following: Enbrel, adalimumab (Humira or adalimumab-adbm), Simponi, Actemra, Orencia, Rinvoq, or Xeljanz (IR or XR). All require prior authorization.

# KORLYM

## Products Affected

- Mifepristone TABS 300MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Not covered for use in patients with type 2 diabetes mellitus that is not associated with Cushing's syndrome. 2) Not covered in pregnant females.
Required Medical Information	Initial criteria: Documentation of failure of surgical treatment or the patient is not a candidate for surgery. Renewal criteria: documentation of a reduction in HbA1c or has reached target HbA1c.
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	1) Documentation of failure of a) insulin therapy and b) one of the following: metformin, a sulfonylurea and a thiazolidinedione.

# KYNMOBI

## Products Affected

- Kynmobi
- Kynmobi Titration Kit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: Documentation that the patient's off time has been reduced with Kynmobi.
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 months. Renewal: Lifetime
Other Criteria	Initial: Documentation of failure of maximum tolerable doses of oral levodopa/carbidopa and one of the following: selegiline, ropinirole, pramipexole, tolcapone and entacapone.

# LAMPIT

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## Products Affected

- Lampit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of Chagas disease caused by T. cruzi confirmed by detection of T. cruzi trypomastigotes on microscopy, detection of T. cruzi DNA by PCR assay, or 2 positive diagnostic serologic tests using two different techniques and antigens showing IgG antibodies to T. cruzi.
Age Restrictions	0 to 18 years of age.
Prescriber Restrictions	Infectious disease specialist or cardiologist.
Coverage Duration	60 days.
Other Criteria	N/A

# LEUPROLIDE

## Products Affected

- Eligard
- Leuprolide Acetate INJ 1MG/0.2ML, 22.5MG
- Lupron Depot (1-month)
- Lupron Depot (3-month)
- Lupron Depot (4-month)
- Lupron Depot (6-month)
- Lupron Depot-ped (1-month)
- Lupron Depot-ped (3-month)

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Gender dysphoria (GD)
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (EM): requires laparoscopic confirmation of diagnosis.
Age Restrictions	Central Precocious Puberty (CPP): for females, age 1 to 11 years. For males, age 1 to 12 years.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, obstetrician/gynecologist, urologist, or endocrinologist.
Coverage Duration	Anemia due to leiomyoma: 3 mo. EM, CPP, uterine leiomyoma: 6 mo. GD: 12 mo. Cancer: Lifetime
Other Criteria	N/A

# LEVOLEUCOVORIN

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## Products Affected

- Levoleucovorin INJ 50MG
- Levoleucovorin Calcium

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Oncologist, rheumatologist, or gastroenterologist
Coverage Duration	12 months
Other Criteria	The following criteria applies to members who newly start on the drug: Medical record documentation of failure of leucovorin or reason why leucovorin cannot be used.

# LIBERVANT

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## Products Affected

- Libervant

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age 2 to 5 years
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# LIDOCAINE PATCHES

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## Products Affected

- Lidocaine PTCH 5%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	1) Diabetic peripheral neuropathy, 2) Cancer neuropathic pain, 3) Chronic back pain, 4) Osteoarthritis of hip or knee.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

# LIRAGLUTIDE

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## Products Affected

- Liraglutide INJ 6MG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of type 2 diabetes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# LITHIUM SOLUTION

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## Products Affected

- Lithium

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime.
Other Criteria	The following criteria only applies to members who newly start on the drug: Medical record documentation of an inability to swallow solid dosage forms.

# LIVDELZI

## Products Affected

- Livdelzi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Confirmation of a diagnosis of primary biliary cholangitis. 2) documentation of an inadequate treatment response to ursodeoxycholic acid (UDCA), or documented contraindication to UDCA. Renewal: 1) documentation of reduction in alkaline phosphatase (ALP) from baseline. 2) Continued use of ursodeoxycholic acid (UDCA) unless there is documentation of intolerance.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a gastroenterologist or hepatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# LIVMARLI

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## Products Affected

- Livmarli SOLN

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of pruritis associated with Alagille syndrome OR cholestatic pruritis due to progressive familial intrahepatic cholestasis (PFIC). Renewal: Medical record documentation of clinical benefit, such as a decrease in pruritis, or improvement in quality of life.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# LIVTENCITY

## Products Affected

- Livtencity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of 1) a history of solid organ transplant or hematopoietic stem cell transplantation, and 2) cytomegalovirus infection/disease.
Age Restrictions	Age at least 12 years
Prescriber Restrictions	Prescribed by, or in consultation with an infectious disease specialist, transplant specialist or oncologist.
Coverage Duration	8 weeks
Other Criteria	Failure of valganciclovir, ganciclovir, cidofovir or foscarnet.

# LODOCO

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## Products Affected

- Lodoco

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of established atherosclerotic cardiovascular disease or multiple risk factors for cardiovascular disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a cardiologist or lipid specialist
Coverage Duration	Lifetime
Other Criteria	Failure of or intolerance to two statins, such as atorvastatin or rosuvastatin.

# LOKELMA

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## Products Affected

- Lokelma

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: medical lab documentation of hyperkalemia. Renewal criteria: reduction in serum potassium from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# LUCEMYRA

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## Products Affected

- Lofexidine Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	14 days
Other Criteria	N/A

# LUMIZYME

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## Products Affected

- Lumizyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Clinical symptoms and biochemical testing indicates alpha-1,4-glucosidase deficiency, and 2) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization of disease progression.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label: 20 mg/kg IV every 2 wk.

# LUPKYNIS

## Products Affected

- Lupkynis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Receiving standard therapy including corticosteroids and immunosuppressants. Renewal: medical record documentation of 1) treatment response such as stabilization of eGFR or no worsening of disease activity and 2) continued use of background immunosuppressant therapy.
Age Restrictions	N/A
Prescriber Restrictions	Nephrologist or rheumatologist
Coverage Duration	12 months.
Other Criteria	Failure of Benlysta (requires prior authorization).

# LYBALVI

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## Products Affected

- Lybalvi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients using opioids or undergoing acute opioid withdrawal.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Failure of two of the following: risperidone, aripiprazole, quetiapine IR and ER, ziprasidone, or asenapine (requires step therapy for new starts).

# MAVYRET

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## Products Affected

- Mavyret

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Detectable HCV RNA (viral load), 2) Documentation of treatment history including response to previous treatment (treatment naïve, previous relapser, partial responder or null responder), and 3) Documentation of presence or absence of cirrhosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance
Other Criteria	N/A

# MAYZENT

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## Products Affected

- Mayzent
- Mayzent Starter Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Lifetime
Other Criteria	Documentation that Mayzent is being requested for monotherapy and is not intended to be used in combination with other multiple sclerosis agents.

# MEBENDAZOLE

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## Products Affected

- Emverm

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record confirmation of an infection caused by <i>Ancylostoma duodenale</i> (common hookworm), <i>Necator americanus</i> (American hookworm), <i>Enterobius vermicularis</i> (pinworm), <i>Trichuris</i> , (whipworm), or <i>Ascaris lumbricoides</i> (common roundworm).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

# MERCAPTOPURINE SUSPENSION

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## Products Affected

- Mercaptopurine SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Documentation of an inability to swallow solid dosage forms.

# METYROSINE

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## Products Affected

- Metyrosine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of scheduled surgical resection or if no surgical intervention planned, documentation of contraindication to surgery or malignant pheochromocytoma.
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist, Oncologist or Nephrologist
Coverage Duration	12 months
Other Criteria	N/A

# MIPLYFFA

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## Products Affected

- Miplyffa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: a) confirmation of a diagnosis of Niemann-Pick disease type C (NPC) by genetic testing, b) documentation of neurologic symptoms due to NPC, and c) documentation that Miplyffa will be prescribed in combination with miglustat.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or neurologist.
Coverage Duration	Lifetime
Other Criteria	N/A

# MODAFINIL

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## Products Affected

- Modafinil TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: documentation of significant improvement in daytime sleepiness and functioning.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: lifetime.
Other Criteria	N/A

# MOTTEGRITY

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## Products Affected

- Prucalopride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of fewer than 3 spontaneous bowel movements per week.
Age Restrictions	Age at least 18 years
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# MOUNJARO

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## Products Affected

- Mounjaro

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of type 2 diabetes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# MOVANTIK

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## Products Affected

- Movantik

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Opioid-induced constipation in adults with chronic non-cancer pain: documentation of fewer than 3 spontaneous bowel movements per week.
Age Restrictions	Age at least 18 years.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

# MULPLETA

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## Products Affected

- Mulpleta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Platelets less than 50k.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a gastroenterologist, hematologist, hepatologist or surgeon.
Coverage Duration	7 days
Other Criteria	Documentation of upcoming procedure.

# MULTAQ

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## Products Affected

- Multaq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	NYHA Class IV heart failure. Symptomatic heart failure with recent decompensation requiring hospitalization.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cardiologist
Coverage Duration	Lifetime
Other Criteria	Documentation of failure of or intolerance to amiodarone.

# MYALEPT

## Products Affected

- Myalept

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: 1) Laboratory test confirming leptin deficiency and 2) Documentation of complications of leptin deficiency such as hyperglycemia, diabetes, hypertriglyceridemia. Renewal criteria: Laboratory test results showing improvement in HbA1c, glucose and triglycerides from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with the FDA approved labeling.

# MYCAPSSA

## Products Affected

- Mycapssa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation showing: 1) a diagnosis of acromegaly, 2) response and tolerance to treatment with octreotide or lanreotide, and 3) that it is not appropriate to continue treatment with injection or depot. Renewal: documentation of IGF-1 normalization or symptom improvement.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# MYFEMBREE

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## Products Affected

- Myfembree

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (EM): requires laparoscopic confirmation of diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ob/gyn specialist
Coverage Duration	24 months
Other Criteria	Failure of or contraindication to oral contraceptives.

# NAGLAZYME

## Products Affected

- Naglazyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Diagnostic confirmation by such as elevation of glycosaminoglycans (GAG) in the urine or deficiency in galactosamine-4-sulfatase enzyme activity, or genetic test confirmation, and 2) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization of disease progression such as improvement in 12-minute walk test, rate of stair climbing, reduction in urinary GAG levels, or reduction in liver or spleen size.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label: 1mg/kg IV once weekly.

# NEMLUVIO

## Products Affected

- Nemludio

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	A) Prurigo nodularis (PN): Initial: medical record confirmation of a diagnosis of prurigo nodularis. Renewal: medical record documentation of a clinical response, such as an improvement in pruritis, a reduction in nodular lesions, or an improvement in functioning. B) Atopic dermatitis (AD): initial: body surface area involvement = 10% at baseline. 2) AD renewal criteria: medical record documentation of a positive treatment response such as a reduction in body surface area involvement, improvement in itching, improvement in functional ability, reduction in the Investigator Global Assessment or Eczema Area and Severity Index from baseline.
Age Restrictions	AD: 12 years of age and older. PN: 18 years of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with a dermatologist.
Coverage Duration	Initial: 6 months Renewal: 12 months
Other Criteria	AD Initial: For patients 12 years of age or older: 1) failure of one of the following very high potency topical steroids: augmented betamethasone, clobetasol or halobetasol and 2) failure of tacrolimus ointment, OR documentation that topical prescription therapies are not appropriate or are contraindicated.

# NERLYNX

## Products Affected

- Nerlynx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of the diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with an oncologist or in certain conditions a hematologist or endocrinologist
Coverage Duration	12 months
Other Criteria	Drug must be prescribed for a FDA approved indication. If not prescribed for a FDA approved indication, the off-label use of the drug must be for a medically accepted indication that is supported by AHFS (American Hospital Formulary Service) Drug Information, NCCN (National Comprehensive Cancer Network) guidelines, Micromedex DrugDex or peer reviewed medical literature in accordance with Chapter 15 of the Medicare Benefit Policy Manual.

# NITAZOXANIDE

## Products Affected

- Nitazoxanide TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Cryptosporidiosis in HIV infected patients
Exclusion Criteria	N/A
Required Medical Information	For diagnosis of cryptosporidiosis in HIV infected patients: documentation that the patient is on antiretroviral therapy (ART) or if the patient is not on ART then ART is being initiated.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Cryptosporidiosis and Giardiasis: 3 days. Cryptosporidiosis, HIV: 14 days.
Other Criteria	For suspension: documentation that the tablet is not indicated for the member's age, or of an inability to take solid oral dosage forms.

# NITYR

## Products Affected

- Nityr

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of diagnostic confirmation of HT1 including laboratory testing (e.g. the presence of succinylacetone and tyrosyl compounds in urine or elevated plasma concentrations of tyrosine and methionine). Renewal: Improvement in urine succinylacetone (SA), liver function tests, alpha-fetoprotein, and serum tyrosine and phenylalanine levels.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# NOXAFIL

## Products Affected

- Noxafil PACK
- Posaconazole
- Posaconazole Dr

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Candidiasis: 1 month. Aspergillosis: 3 months. Prophylaxis of invasive fungal infections: 6 months.
Other Criteria	For oropharyngeal candidiasis or prophylaxis of invasive fungal infections in a patient who has received a hematopoietic stem-cell transplant or has chemotherapy-induced neutropenia due to hematologic malignancy: failure of fluconazole or itraconazole. For suspension only: documentation of an inability to swallow solid oral dosage forms.

## NUCALA

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### Products Affected

- Nucala

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>1) For severe asthma with eosinophilic phenotype: Initial criteria: a) Medical record documentation of diagnosis and b) Blood eosinophil levels greater than 150 cells/mcL at baseline or greater than or equal to 300 cells/mcL. Renewal criteria: documentation of or claims history showing a reduction in the use of oral steroids or reduction in asthma symptoms. 2) For eosinophilic granulomatosis with polyangiitis: Initial criteria: a) diagnosis confirmed by documentation of asthma, blood eosinophil level of 10% or an absolute count of greater than 1000 cells/mm<sup>3</sup>, and systemic vasculitis involving two or more extra-pulmonary organs. Renewal criteria: documentation of response to treatment such as achievement of remission, decrease in the use of steroids, decrease in the rate of relapses or improvement in asthma symptoms. 3) For hypereosinophilic syndrome (HES): Initial criteria: Medical record documentation showing that the diagnosis has a duration of at least 6 months, and does not have an identifiable nonhematologic secondary cause. Renewal: documentation of reduction in flares, or other clinical benefit from Nucala. 4) For the treatment of nasal polyps: Initial: a) documentation that Nucala is being used as add-on therapy, and b) documentation of an inadequate response to nasal corticosteroids. Renewal: Documentation of clinical benefit from Nucala.</p>
<b>Age Restrictions</b>	Age at least 6 years for asthma with eosinophilic phenotype.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a rheumatologist, pulmonologist, allergist, immunologist, vasculitis specialist, hematologist. EENT or otolaryngologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	For severe asthma with eosinophilic phenotype: Failure of an inhaled corticosteroid and a long-acting beta agonist.

# NUEDEXTA

## Products Affected

- Nuedexta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Complete atrioventricular block without implanted pacemaker or is at high risk for complete AV block.2) Concomitant use with drugs containing quinidine, quinine, mefloquine, drugs that prolong the QT interval and are metabolized by CYP2D6 (thioridazine and pimozide), monoamine oxidase inhibitors. 3) Heart failure. 4) Prolonged QT interval, congenital long QT syndrome or history suggesting torsades de pointes.
Required Medical Information	Renewal criteria: documentation of clinical benefit such as improvement in the Center for Neurologic Study Lability Scale or reduction in the number of laughing and crying episodes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	N/A

# NULOJIX

## Products Affected

- Nulojix

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation that Epstein-Barr virus status is positive.
Age Restrictions	N/A
Prescriber Restrictions	Nephrologist or transplant specialist
Coverage Duration	Lifetime
Other Criteria	To prevent or treat an organ transplant rejection, Part B versus D determination will be made to determine coverage. If the drug is to be covered by Part D and the patient is newly started on Nulojix, documentation of failure of tacrolimus and cyclosporine. Nulojix should be used in combination with basiliximab induction, mycophenolate mofetil and corticosteroids.

# NUPLAZID

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## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Medical record documentation of failure of or intolerance to clozapine or reason why clozapine cannot be used.

# NURTEC

## Products Affected

- Nurtec

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Episodic migraine, initial: medical record documentation of 4-14 headache days per month. Episodic migraine, renewal: documentation of treatment response such as a decrease in the number of migraine days, less migraine episodes, decreased abortive medication usage, or emergency room visits related to migraine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Episodic migraine, initial: 6 months. Episodic renewal: 12 months. Acute migraine: lifetime
Other Criteria	1) Episodic migraine, initial: failure of propranolol and topiramate. 2) Acute migraine treatment: Failure of two triptans such as eletriptan, sumatriptan, naratriptan, rizatriptan, or zolmitriptan. If triptans are contraindicated: failure of 1) naproxen and 2) one other NSAID such as ibuprofen, diclofenac, flurbiprofen or celecoxib.

# Ocaliva

## Products Affected

- Ocaliva

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Used in combination with ursodeoxycholic acid (UDCA) unless there is documentation of intolerance. Renewal: 1) Documentation of a reduction in alkaline phosphatase (ALP) from baseline. 2) Continued use of ursodeoxycholic acid (UDCA) unless there is documentation of intolerance.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a gastroenterologist, hepatologist or GI specialist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Initial: Failure to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 months of ursodeoxycholic acid (UDCA), or documented contraindication to UDCA.

# OCREVUS

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## Products Affected

- Ocrevus
- Ocrevus Zunovo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	N/A

# OMNIPOD

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## Products Affected

- Omnipod 5 Dexcom G7g6 Intro Kit (gen 5)
- Omnipod 5 Dexcom G7g6 Pods (gen 5)
- Omnipod 5 G7 Intro Kit (gen 5)
- Omnipod 5 G7 Pods (gen 5)
- Omnipod 5 Libre2 Plus G6
- Omnipod 5 Libre2 Plus G6 Pods
- Omnipod Classic Pdm Starter Kit (gen 3)
- Omnipod Classic Pods (gen 3)
- Omnipod Dash Intro Kit (gen 4)
- Omnipod Dash Pdm Kit (gen 4)
- Omnipod Dash Pods (gen 4)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For all: a diagnosis of diabetes. The following criteria apply to those age 21 and older: 1) the member completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen: a) Glycosylated hemoglobin level (HbA1c) greater than 7.0%, b) History of recurring hypoglycemia, c) Wide fluctuations in blood glucose before mealtime, d) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl, or e) History of severe glycemic excursions. OR 2) the member has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	N/A

# OPFOLDA

## Products Affected

- Opfolda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) medical record documentation of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) not improving on current enzyme replacement therapy, 2) weight of at least 40kg, and 3) documentation that Opfolda will be used in combination with cipagluosidase alfa-atga.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# OPIPZA

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## Products Affected

- Opiqua

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: documentation of an inability to swallow solid oral dosage forms.

# OPIUM TINCTURE

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## Products Affected

- Opium
- Opium Tincture TINC 1%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Failure of or contraindication to diphenoxylate/atropine and loperamide.

# OPSUMIT

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## Products Affected

- Opsumit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pregnancy
Required Medical Information	Documentation of World Health Organization (WHO) functional class II-IV.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist or Cardiologist
Coverage Duration	Lifetime
Other Criteria	Failure of or contraindication to 1) sildenafil or tadalafil and 2) bosentan or ambrisentan. All require prior authorization.

# ORAL IMMUNOTHERAPY

## Products Affected

- Grastek
- Odactra
- Ragwitek

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For Grastek: documentation of a positive skin test or pollen specific IgE antibodies to Timothy grass or cross-reactive grass pollens. For Odactra, documentation of a positive skin test to licensed house dust mite allergen extracts or positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites.
Age Restrictions	Age 65 years of age or younger
Prescriber Restrictions	Allergist or Immunologist
Coverage Duration	Lifetime
Other Criteria	Failure of or contraindication to 1) an oral or nasal antihistamine (e.g., cetirizine, levocetirizine, loratadine, azelastine nasal spray) and 2) an intranasal corticosteroid (e.g., fluticasone or flunisolide nasal spray)

# ORAL RIBAVIRIN

## Products Affected

- Ribavirin CAPS
- Ribavirin TABS 200MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Detectable HCV RNA (viral load), 2) Documentation of treatment history including response to previous treatment (treatment naïve, previous relapser, partial responder or null responder), and 3) Documentation of presence or absence of cirrhosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance
Other Criteria	Ribavirin will be approved consistent with FDA approved labeling or AASLD/IDSA guidelines as part of treatment regimens consisting of ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, and Pegasys if criteria for these drugs are met. For non-formulary drugs such as Sovaldi or Daklinza approved based on the prescriber's supporting statement that all formulary drugs would not be as effective or safe as the non-formulary drug, ribavirin will be approved as requested consistent with FDA approved labeling or AASLD/IDSA guidelines.

# ORAL TRANSMUCOSAL FENTANYL

## Products Affected

- Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Not approved for use of acute or postoperative pain and for opioid non-tolerant patients.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Oncologist or Pain Specialist
Coverage Duration	12 months
Other Criteria	Documentation of 1) Failure of two short-acting opioids (eg, oxycodone, morphine sulfate, etc) or an inability to swallow, dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting AND 2) Patient is on or will be on a long-acting narcotic (eg, methadone, morphine sulfate ER, oxycodone ER, fentanyl), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate).

# ORENCIA

## Products Affected

- Orencia
- Orencia Clickject

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Rheumatoid arthritis (RA) and juvenile idiopathic arthritis (JIA) Renewal: Improved functioning and/or improvement in tender joint count and swollen joint count. 2) Psoriatic Arthritis (PsA) Renewal: Improved functioning and/or decreased in the number of tender, swollen joints and reduction in skin lesions and/or has disease stability. 3) Prophylaxis of acute graft versus host disease (aGVHD): a) documentation that Orencia will be used with a calcineurin inhibitor and methotrexate, and b) documentation that the patient will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.
Age Restrictions	JIA: age at least 6 years for Orencia IV and age at least 2 years for Orencia Subcutaneous Injection
Prescriber Restrictions	RA, JIA: rheumatologist. PsA: dermatologist or rheumatologist. aGVHD: hematologist, oncologist or transplant specialist.
Coverage Duration	RA, JIA, PsA initial: 6 months. Renewal: 12 months. aGVHD: 28 days
Other Criteria	RA initial: failure of methotrexate and at least one other DMARD such as leflunomide, sulfasalazine, or hydroxychloroquine. JIA initial: failure of an 8-week trial of methotrexate.

# ORFADIN

## Products Affected

- Nitisinone
- Orfadin SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of diagnostic confirmation of HT1 including laboratory testing (e.g. the presence of succinylacetone and tyrosyl compounds in urine or elevated plasma concentrations of tyrosine and methionine). Renewal: Improvement in urine succinylacetone (SA), liver function tests, alpha-fetoprotein, and serum tyrosine and phenylalanine levels.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label: initial 1 mg/kg/day (divided into 2 doses) titrated to achieve suppression of SA, maximum 2 mg/kg/day. For Orfadin Suspension: Documentation of an inability to swallow solid dosage forms.

# ORGOVYX

## Products Affected

- Orgovyx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of an FDA approved or medically accepted indication.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with Oncologist or Urologist
Coverage Duration	Lifetime
Other Criteria	N/A

# ORIAHNN

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## Products Affected

- Oriahnn

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ob/gyn specialist.
Coverage Duration	24 months
Other Criteria	Failure of or contraindication to: 1) oral contraceptives and 2) tranexamic acid.

# ORILISSA

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## Products Affected

- Orilissa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (EM): requires laparoscopic confirmation of diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ob/gyn specialist
Coverage Duration	EM: 24 months. EM with dyspareunia: 6 months. EM with moderate hepatic impairment: 6 months.
Other Criteria	N/A

# ORKAMBI

## Products Affected

- Orkambi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Medical record documentation of a diagnosis of cystic fibrosis homozygous for the F508del mutation confirmed using an FDA-cleared cystic fibrosis mutation test. Renewal criteria: Medical record documentation of treatment response such as an improvement in FEV1, reduction in pulmonary exacerbation, or improvement in respiratory symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	For Orkambi Pack (Suspension): documentation of an inability to swallow solid dosage forms.

# ORLADEYO

## Products Affected

- Orladeyo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Documentation of hereditary angioedema Type I and II confirmed by genetic testing, or complement studies of C4, C1INH antigenic and C1INH functional levels supporting the diagnosis. For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history. Renewal: Documentation of reduction in the number of angioedema attacks, significant improvement in the severity and duration of attacks, or documentation of functional improvement.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, allergist or an immunologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Failure of, intolerance to, or contraindication to two of the following: Cinryze, Haegarda, Takzyro. All require prior authorization.

# OTEZLA

## Products Affected

- Otezla

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Bechet's syndrome (BS) initial: medical record documentation of oral ulcer's caused by Bechet's syndrome. BS renewal: medical record documentation of reduction in severity of oral ulcers or improvement in symptoms. 2) Plaque psoriasis (PsO) initial: involvement of more than 2% of body surface area or hand, foot, face, or genital involvement. PsO renewal: improvement in affected BSA, plaque severity and/or functioning. 3) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count.
Age Restrictions	N/A
Prescriber Restrictions	BS: rheumatologist. PsO: dermatologist. PsA: rheumatologist or dermatologist
Coverage Duration	Initial: 6 months. Renewal: 12 months
Other Criteria	PsO Initial: failure of 1) one topical agent such as a corticosteroid (i.e. betamethasone or clobetasol), calcipotriene, tazarotene (requires prior authorization), or tacrolimus and 2) methotrexate or cyclosporine.

# OXBRYTA

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## Products Affected

- Oxbryta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: documentation of improvement in hemoglobin from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Failure of hydroxyurea.

# OXERVATE

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## Products Affected

- Oxervate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Documentation of an active ocular infection or inflammation not related to neurotrophic keratitis in affected eye, or ocular disease requiring topical treatment in the affected eye.
Required Medical Information	Medical record documentation of neurotrophic keratitis.
Age Restrictions	Age at least 2 years.
Prescriber Restrictions	Ophthalmologist
Coverage Duration	8 weeks
Other Criteria	N/A

# OXYCODONE ER

## Products Affected

- Oxycodone Hcl Er T12A 10MG, 20MG, 40MG, 80MG
- Oxycodone Hydrochloride Er T12A 10MG, 20MG, 40MG
- Oxycontin T12A

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Failure of sustained release morphine sulfate and not receiving concurrent therapy with another long-acting opioid, such as fentanyl or sustained release morphine sulfate.

# OZEMPIC

## Products Affected

- Ozempic INJ 2MG/3ML, 4MG/3ML, 8MG/3ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of type 2 diabetes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# PALIFERMIN

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## Products Affected

- Kepivance INJ 6.25MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Oncologist
Coverage Duration	7 days
Other Criteria	N/A

# PALIPERIDONE ER INJECTION

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## Products Affected

- Invega Hafyera
- Invega Trinza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The following criteria applies to members who newly start on the drug. 1) For Invega Hafyera: medical record documentation or evidence from claims history that Invega Sustenna has been used for 4 months OR that Invega Trinza has been used for 3 months. 2) For Invega Trinza: medical record documentation or evidence from claims history that Invega Sustenna has been used for 4 months.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# PALYNZIQ

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## Products Affected

- Palynziq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Phenylalanine level (Phe) at or above 600 micromol/L. Renewal: Reduction in Phe levels.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: Lifetime
Other Criteria	N/A

# PANRETIN

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## Products Affected

- Panretin

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of cutaneous lesions associated with AIDS-related Kaposi's sarcoma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# PARENTERAL BISPHOSPHONATES

## Products Affected

- Pamidronate Disodium INJ 30MG/10ML, 6MG/ML, 90MG/10ML
- Zoledronic Acid INJ 4MG/100ML, 4MG/5ML, 5MG/100ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For hypercalcemia of malignancy: albumin-corrected serum calcium above 12mg/dL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	1) For the diagnosis of osteoporosis: failure of two oral bisphosphonates such as ibandronate and alendronate or reason why bisphosphonates cannot be used. Risedronate is available after failure of ibandronate and alendronate. 2) For end stage renal disease (ESRD) patients on dialysis, Part B versus Part D determination will be made to determine if the drug prescribed will be used for an ESRD-related condition. For ESRD-related conditions, the drug will be covered under Part B and provided by the dialysis center.

# PARICALCITOL

## Products Affected

- Paricalcitol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Hypercalcemia and vitamin D toxicity.
Required Medical Information	1) Stage 3 Chronic Kidney Disease (CKD): a) GFR 30-59, b) iPTH at least 70 pg/mL, c) serum calcium less than 9.5 mg/dL, d) serum phosphorus less than or equal to 4.6 mg/dL. 2) Stage 4 CKD: a) GFR 15-29, b) iPTH greater than 110 pg/mL, c) serum calcium less than 9.5 mg/dL, d) serum phosphorus less than or equal to 4.6 mg/dL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	1) Failure of or intolerance to calcitriol or reason why calcitriol cannot be used. 2) For end stage renal disease (ESRD) patients, Part B versus Part D determination will be made to determine if the drug prescribed will be used for an ESRD-related condition. For ESRD-related conditions, the drug will be covered under Part B and provided by the dialysis center.

## PAROXETINE SUSPENSION

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### Products Affected

- Paroxetine Hydrochloride SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Documentation of 1) An inability to take solid oral dosage forms and 2) Failure of or contraindication to sertraline solution.

# PEGASYS

## Products Affected

- Pegasys

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) For the treatment of hepatitis B (HBV): a) Compensated cirrhosis and HBV DNA greater than 2000 IU/ml or b) If HBeAg positive, HBV DNA at least 20,000 IU/ml and serum ALT is persistently elevated after 3-6 months or liver biopsy shows at least moderate inflammation or significant fibrosis or c) If HBeAg negative, HBV DNA greater than 2000 IU/ml and serum ALT is persistently elevated after 3-6 months or liver biopsy shows at least moderate inflammation or fibrosis. 2) For the treatment of hepatitis C (HCV): Detectable HCV RNA (viral load), 2) Documentation of treatment history including response to previous treatment (treatment naive, previous relapser, partial responder or null responder), and 3) Documentation of presence or absence of cirrhosis.
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist, infectious disease specialist, Hepatitis C specialist or hepatologist
Coverage Duration	HBV 12 mo. HCV: 48 weeks
Other Criteria	For the treatment of Hepatitis C, pegylated interferon is no longer standard of care. Refer to criteria for Mavyret, sofosbuvir/velpatasvir, ledipasvir/sofosbuvir, and Vosevi.

# PENBRAYA

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## Products Affected

- Penbraya

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age between 10 years and 25 years.
Prescriber Restrictions	N/A
Coverage Duration	2 doses in 6 months
Other Criteria	N/A

## PENTAMIDINE

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### Products Affected

- Pentamidine Isethionate INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an infectious disease specialist, a transplant specialist, an oncologist, or a hematologist.
Coverage Duration	21 days
Other Criteria	N/A

# PIMECROLIMUS

## Products Affected

- Pimecrolimus

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications, Some Medically accepted Indications.
<b>Off-Label Uses</b>	Primary cutaneous lymphomas
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For treatment of primary cutaneous lymphomas: documentation of mycosis fungoides.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with a dermatologist or oncologist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	For treatment of atopic dermatitis, initial: failure of 1) tacrolimus ointment and 2) if older than 12 years of age: a high potency steroid such as clobetasol.

# PLERIXAFOR

## Products Affected

- Plerixafor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Oncologist and hematologist
Coverage Duration	4 days
Other Criteria	Use in combination with a granulocyte colony stimulating factor.

# PRALUENT

## Products Affected

- Praluent

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	A) For secondary prevention for patients with established atherosclerotic cardiovascular disease (ASCVD): LDL-C greater than 55 mg/dL. B) Primary heterozygous familial hypercholesterolemia (HeFH) initial: 1) LDL-C greater than 100 mg/dL without ASCVD, or greater than 55 mg/dL with ASCVD. C) Primary hypercholesterolemia initial: LDL-C greater than 100 mg/dL without ASCVD, or greater than 55 mg/dL with ASCVD. D) Homozygous familial hypercholesterolemia (HoFH) initial: diagnosis confirmed by a) genetic testing or b) documentation of either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, AND either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents. Renewal criteria for all indications: 1) Continuance of treatment with statins unless contraindicated or the patient is unable to tolerate and 2) LDL reduction.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a cardiologist, endocrinologist or lipid specialist
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	For all indications: Medical record documentation of failure of, documented contraindications, or intolerance or significant side effects on one high-intensity statin therapy such as atorvastatin 40mg-80mg or rosuvastatin 20mg-40mg for 12 weeks. Contraindications and significant side effects to statins include evidence of rhabdomyolysis or persistent myalgia or myositis.

# PRENATAL VITAMINS

## Products Affected

- Pnv Prenatal Plus Multivitamin + Dha
- Prenatal TABS 120MG; 0; 200MG; 10MCG; 2MG; 12MCG; 27MG; 1MG; 20MG; 10MG; 1200MCG; 3MG; 1.84MG; 10MG; 25MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Male gender
Required Medical Information	N/A
Age Restrictions	Prior authorization is not required for patients under the age of 51. Prior authorization is required for patients 51 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# PRETOMANID

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## Products Affected

- Pretomanid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Drug-sensitive tuberculosis, latent infection due to Mycobacterium tuberculosis, extra-pulmonary infection due to Mycobacterium tuberculosis, or MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy.
Required Medical Information	Medical record documentation of 1) Extensively drug resistant pulmonary tuberculosis confirmed by culture and drug sensitivity, 2) Pretomanid will be used in combination with Sirturo and linezolid.
Age Restrictions	N/A
Prescriber Restrictions	Infectious Disease or tuberculosis (TB) specialist
Coverage Duration	26 weeks
Other Criteria	N/A

# PREVYMIS

## Products Affected

- Prevymis INJ
- Prevymis TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of 1) the patient is receiving or will receive an allogenic hematopoietic stem cell transplant and is at risk for cytomegalovirus (CMV) infection because of the patient's CMV-seropositive status or the donor's status. OR 2) that the patient is receiving or will receive a kidney transplant and is at high risk of CMV infection.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	200 days
Other Criteria	N/A

# PROMACTA

## Products Affected

- Eltrombopag Olamine
- Promacta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For chronic immune (idiopathic) thrombocytopenic purpura (ITP): 1) Initial criteria: Medical record documentation of platelet count less 30,000 per mm <sup>3</sup> . 2) Renewal criteria: maintenance of platelet counts between 30,000 per mm <sup>3</sup> and 150,000 per mm <sup>3</sup> or an increase in platelet counts from baseline with resolution of bleeding episodes. For thrombocytopenia in patients with chronic Hepatitis C: 1) Initial criteria: a) Platelets less than 75,000 per mm <sup>3</sup> . b) Request to treat thrombocytopenia to allow initiation of interferon-based therapy. 2) Renewal criteria: medical record documentation that platelets have increased since initiating Promacta. For the treatment of aplastic anemia (AA): 1) Initial criteria: platelets counts less than or equal to 30,000 per mm <sup>3</sup> . 2) Renewal criteria: maintenance of platelet counts between 30,000 per mm <sup>3</sup> and 150,000 per mm <sup>3</sup> or an increase in platelet counts from baseline.
Age Restrictions	Age at least 1 year.
Prescriber Restrictions	For ITP: Hematologist or Oncologist. For hepatitis C, thrombocytopenia: Hematologist, GI specialist, Hepatologist, Infectious Disease specialist or Oncologist. For aplastic anemia: Hematologist or Oncologist.
Coverage Duration	ITP: Initial 6wk, Renew 6mo. HepC, thrombo: Initial 3mo, Renew 12mo. AA: Initial 4mo, Renew 12mo.
Other Criteria	The following criteria only applies to chronic immune (idiopathic) thrombocytopenia: documentation of disease refractory to the following: systemic corticosteroids, immunoglobulin replacement or splenectomy. For suspension: documentation of an inability to swallow solid oral dosage forms.

## PULMONARY FIBROSIS AGENTS

### Products Affected

- Ofev
- Pirfenidone

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	A) Idiopathic pulmonary fibrosis, initial criteria: medical record documentation of the diagnosis of idiopathic pulmonary fibrosis based on the presence of a usual interstitial pneumonia pattern on high-resolution computed tomography or surgical lung biopsy. B) Systemic sclerosis-associated interstitial lung disease, initial, (Ofev only): medical record documentation of systemic sclerosis-associated interstitial lung disease. Renewal criteria (all diagnoses): medical record documentation of a decrease in the decline in force vital capacity (FVC).
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist
Coverage Duration	12 months
Other Criteria	N/A

## PYRUKYND

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### Products Affected

- Pyrukynd
- Pyrukynd Taper Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: medical record documentation of a diagnosis of hemolytic anemia with pyruvate kinase deficiency confirmed by genetic testing. Renewal: documentation of a reduction in transfusion requirements from baseline.
Age Restrictions	Age of at least 18 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, or genetic specialist
Coverage Duration	6 months.
Other Criteria	N/A

# QUININE SULFATE

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## Products Affected

- Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A

# RADICAVA

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## Products Affected

- Edaravone
- Radicava
- Radicava Ors
- Radicava Ors Starter Kit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist or a specialist in Amyotrophic Lateral Sclerosis (ALS)
Coverage Duration	12 months
Other Criteria	N/A

# RALDESY

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## Products Affected

- Raldesy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs.
Required Medical Information	1) Medical record documentation of a diagnosis of major depressive disorder.
Age Restrictions	Age of at least 18 years.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: documented inability to swallow solid oral dosage forms.

# RAVICTI

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## Products Affected

- Ravicti

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis confirmed by DNA testing. Renewal: Medical record documentation of stabilization of disease progression such as stabilization of neurologic impairments or seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Failure of sodium phenylbutyrate powder (requires prior authorization).

# REGRANEX

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## Products Affected

- Regranex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Neoplasm at the application site.
Required Medical Information	Renewal: documentation of a reduction in ulcer size by approximately 30% after 10 weeks of treatment.
Age Restrictions	N/A
Prescriber Restrictions	Surgeon, Podiatrist, Endocrinologist or Infectious Disease Specialist
Coverage Duration	Initial: 3 months. Renewal: 2 months.
Other Criteria	N/A

# RELISTOR

## Products Affected

- Relistor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Known or suspected mechanical gastrointestinal obstruction.
Required Medical Information	1) For the treatment of opioid-induced constipation in patients with advanced illness receiving palliative care: a) Receiving palliative care for advanced illness and b) Receiving chronic opioid therapy. 2) For the treatment of opioid-induced constipation in patients with chronic noncancer pain: a) documentation of less than 3 spontaneous bowel movements per week b) Receiving chronic opioid therapy for at least one month.
Age Restrictions	Age at least 18 years
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	For the treatment of opioid-induced constipation in patients receiving palliative care and using injections, dosing consistent with product label: a) 38 kg to less than 62 kg, 8 mg/dose. b) 62 kg to 114 kg, 12 mg/dose. c) Less than 38 kg or greater than 114 kg, 0.15/kg/dose.

# RELYVRIO

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## Products Affected

- Relyvrio

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS).
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or ALS specialist.
Coverage Duration	Lifetime
Other Criteria	N/A

# REPATHA

## Products Affected

- Repatha
- Repatha Pushttronex System
- Repatha Sureclick

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	A) For secondary prevention for patients with established atherosclerotic cardiovascular disease (ASCVD): LDL-C greater than 55 mg/dL. B) Primary heterozygous familial hypercholesterolemia (HeFH) initial: 1) LDL-C greater than 100 mg/dL without ASCVD, or greater than 55 mg/dL with ASCVD. C) Primary hypercholesterolemia initial: LDL-C greater than 100 mg/dL without ASCVD, or greater than 55 mg/dL with ASCVD. D) Homozygous familial hypercholesterolemia (HoFH) initial: diagnosis confirmed by a) genetic testing or b) documentation of either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, AND either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents. Renewal criteria for all indications: 1) Continuance of treatment with statins unless contraindicated or the patient is unable to tolerate and 2) LDL reduction.
Age Restrictions	N/A
Prescriber Restrictions	Cardiologist, Endocrinologist or Lipid Specialist
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	For all indications: Medical record documentation of failure of, documented contraindications, or intolerance or significant side effects on one high-intensity statin therapy such as atorvastatin 40mg-80mg or rosuvastatin 20mg-40mg for 12 weeks. Contraindications and significant side effects to statins include evidence of rhabdomyolysis or persistent myalgia or myositis.

# REVCovi

## Products Affected

- Revcovi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: laboratory result confirmation of a diagnosis of adenosine deaminase severe combined immune deficiency (ADASCID). Renewal: medical record documentation of a clinical response to Revcovi, and that monitoring recommended per the FDA labeling is being completed.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an immunologist.
Coverage Duration	12 months
Other Criteria	N/A

# REYVOW

## Products Affected

- Reyvow

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Failure of two triptans such as eletriptan, sumatriptan, naratriptan, rizatriptan, or zolmitriptan. If triptans are contraindicated: failure of 1) naproxen and 2) one other NSAID such as ibuprofen, diclofenac, flurbiprofen or celecoxib.

# REZDIFFRA

## Products Affected

- Rezdiffra

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: a) Medical record documentation of noncirrhotic nonalcoholic steatohepatitis (NASH). 2) Documentation of moderate to advanced liver fibrosis, Stage F2 or F3.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a hepatologist or gastroenterologist
Coverage Duration	Lifetime
Other Criteria	N/A

# REZUROCK

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## Products Affected

- Rezurock

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Medical record documentation of a diagnosis of chronic graft vs host disease.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an oncologist, hematologist, or transplant specialist.
Coverage Duration	Lifetime
Other Criteria	For patients age 18 and older: Failure of 1) Jakafi and 2) Imbruvica. Both require prior authorization. For patients age 12 to 17: Failure of Jakafi.

# RINVOQ

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## Products Affected

- Rinvoq
- Rinvoq Lq

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Rheumatoid arthritis (RA) initial: documentation of an inadequate response or intolerance to one or more TNF inhibitors (such as Humira or Enbrel). RA renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 2) Psoriatic arthritis (PsA) initial: documentation of an inadequate response or intolerance to one or more TNF inhibitor (such as Humira, Enbrel, or Simponi). PsA renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 3) Atopic dermatitis (AD) initial: body surface area involvement of at least 10% at baseline. AD renewal: medical record documentation of a positive treatment response such as a reduction in body surface area involvement, improvement in itching, or improvement in functional ability, reduction in the Investigator Global Assessment or Eczema Area and Severity Index from baseline. 4) Ulcerative colitis (UC) or Crohn's disease (CD): initial: documentation of an inadequate response or intolerance to one or more TNF inhibitor (such as Humira or Simponi). UC or CD renewal: medical record documentation of treatment response such as decrease in symptoms, fistulas or bloody stools per day, elimination of signs of toxicity, or clinical remission. 5) Ankylosing spondylitis (AS) renewal: improved functioning and/or signs and symptoms of AS. 6) Non-radiographic axial spondyloarthritis renewal: improved functioning and/or improvement in signs and symptoms of non-radiographic axial spondyloarthritis. 7) Polyarticular juvenile idiopathic arthritis (pJIA): initial: documentation of an inadequate response or intolerance to one or more TNF inhibitor (such as adalimumab). pJIA renewal: improved functioning and/or improvement in tender joint count and swollen joint count.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, pJIA, AS and non-radiographic axial spondyloarthritis: prescribed by or in consultation with a rheumatologist. PsA: prescribed by or in consultation with a dermatologist or rheumatologist. AD: prescribed by or in consultation with a dermatologist, allergist or immunologist. UC or CD: prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.

<b>Other Criteria</b>	<p>Rheumatoid arthritis initial: failure of methotrexate and at least one other DMARD such as leflunomide, sulfasalazine, or hydroxychloroquine.</p> <p>Atopic dermatitis initial: Failure of or contraindication to 1) one of the following very high potency topical steroids: augmented betamethasone, clobetasol or halobetasol and 2) tacrolimus ointment. Ankylosing spondylitis and non-radiographic axial spondyloarthritis, initial: failure of one non-steroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac. pJIA initial: failure of an 8 week trial of methotrexate.</p>
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# RITUXIMAB

## Products Affected

- Riabni
- Rituxan
- Ruxience
- Truxima

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) renewal: medical record documentation of a 20% or greater improvement in tender joint count and swollen joint count or a reduction in specific, objective pain symptoms and/or improved functioning.
Age Restrictions	Age at least 18 years.
Prescriber Restrictions	Oncologist, Rheumatologist or Dermatologist.
Coverage Duration	NHL, CLL, WG, MPA and pemphigus vulgaris: Lifetime. RA Initial: 6 months. RA Renewal: 12 months.
Other Criteria	N/A

# RIVFLOZA

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## Products Affected

- Rivfloza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Confirmation of primary hyperoxaluria type 1 (PH1) with elevated urinary oxalate excretion and genetic testing. Renewal: medical record documentation of reduction in urinary oxalate excretion.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# ROZLYTREK PELLETS

## Products Affected

- Rozlytrek PACK

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of the diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an oncologist.
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to new starts only. Initial: Documentation of an inability to swallow solid oral dosage forms. Drug must be prescribed for a FDA approved indication or a medically accepted indication that is supported by AHFS (American Hospital Formulary Service) Drug Information or Micromedex for non-cancer indications, and supported by NCCN Compendium, Clinical Pharmacology, Lexi-Drugs, and acceptable medical journals for cancer indications.

## RSV VACCINE

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### Products Affected

- Arexvy
- Mresvia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prior authorization does not apply to members age 50 years or older for Arexvy, and does not apply to members age 60 years or older for Mresvia.
Age Restrictions	Minimum age of 50 years for Arexvy and 60 years for Mresvia.
Prescriber Restrictions	N/A
Coverage Duration	1 month for 1 dose
Other Criteria	N/A

## RUFINAMIDE SUSPENSION

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### Products Affected

- Rufinamide SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: documentation of an inability to take solid oral dosage forms.

# RYBELSUS

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## Products Affected

- Rybelsus TABS 14MG, 3MG, 7MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of type 2 diabetes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# RYTARY

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## Products Affected

- Rytary

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Prescribed by or in consultation with a neurologist or movement disorder specialist.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Failure of carbidopa/levodopa ER tablets.

# SANDOSTATIN LAR

## Products Affected

- Octreotide Acetate INJ 10MG, 20MG, 30MG
- Sandostatin Lar Depot

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) For the treatment of acromegaly: a) Initial: medical record documentation of failure of surgery, radiation or bromocriptine or reason or reason why surgery, radiation or bromocriptine are not options. b) Renewal: documentation of IGF-1 normalization or symptom improvement. 2) Renewal criteria for all other conditions: reduction in symptoms such as stool frequency.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For the treatment of acromegaly, metastatic carcinoid tumors and vasoactive intestinal peptide tumors: documentation of response to and tolerance to octreotide immediate release injection.

# SAPHNELO

## Products Affected

- Saphnelo

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Severe active CNS lupus or used in combination with IV cyclophosphamide
<b>Required Medical Information</b>	Initial criteria: 1) Medical record documentation of a diagnosis of systemic lupus erythematosus (SLE) and is auto-antibody positive as defined as Antinuclear antibody (ANA titer) greater than or equal to 1:80 or anti-double stranded DNA antibody (Anti-dsDNA) greater than or equal to 30 IU/ml. 2) Receiving standard therapy including NSAIDs, antimalarials, corticosteroids or immunosuppressants. Renewal criteria: medical record documentation of treatment response such as an improvement in the SELENA-SLEDAI score or no worsening of disease activity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with a rheumatologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months
<b>Other Criteria</b>	N/A

# SAPROPTERIN

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## Products Affected

- Javygtor PACK 500MG
- Javygtor TABS
- Sapropterin Dihydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: Documentation of response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: Lifetime.
Other Criteria	N/A

# SAVELLA

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## Products Affected

- Savella
- Savella Titration Pack

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of fibromyalgia.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Failure of two of the following: pregabalin, duloxetine, or amitriptyline.

# SCOPOLAMINE

## Products Affected

- Scopolamine PT72 1MG/3DAYS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Excessive salivation prophylaxis
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Post-op nausea and vomiting and motion sickness: 1 month. Excessive salivation: 12 months.
Other Criteria	For the treatment of motion sickness: failure of or intolerance to meclizine.

## SECUADO

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### Products Affected

- Secuado

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Documentation of failure of, intolerance to, or contraindication to asenapine sublingual tablets (requires step therapy for new starts).

# SIGNIFOR

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## Products Affected

- Signifor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal criteria: decrease in urinary free cortisol or improvement in signs or symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist
Coverage Duration	Initial: 3 months. Renewal: Lifetime.
Other Criteria	N/A

# SIKLOS

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## Products Affected

- Siklos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of sickle cell anemia with crisis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# SILDENAFIL

## Products Affected

- Sildenafil Citrate SUSR
- Sildenafil Citrate TABS 20MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concurrent therapy with nitrates.
Required Medical Information	Documentation of New York Heart Association (NYHA) Functional Class II-IV.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist or Cardiologist
Coverage Duration	Lifetime
Other Criteria	For oral suspension: documentation of a reason why sildenafil tablets cannot be used such as failure, inability to swallow oral dosage form, or contraindication that is also not a contraindication to the suspension.

# SIMPONI

## Products Affected

- Simponi
- Simponi Aria

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Rheumatoid arthritis (RA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 2) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count. 3) Ankylosing spondylitis (AS) renewal: improved functioning and/or signs and symptoms of AS. 4) Ulcerative Colitis (UC) renewal: medical record documentation of treatment response such as decrease in bloody stools per day, elimination of signs of toxicity, or clinical remission.
Age Restrictions	N/A
Prescriber Restrictions	Rheumatoid arthritis, ankylosing spondylitis: rheumatologist. Psoriatic arthritis: dermatologist or rheumatologist. Ulcerative colitis: gastroenterologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	RA initial: failure of or contraindication to methotrexate and at least one other DMARD such as leflunomide, sulfasalazine, or hydroxychloroquine. AS initial: failure of one oral nonsteroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac.

# SIRTURO

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## Products Affected

- Sirturo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of 1) multi-drug resistant pulmonary tuberculosis confirmed by culture and drug sensitivity and must be resistant to at least isoniazid and rifampin, 2) Other effective regimens cannot be offered.
Age Restrictions	N/A
Prescriber Restrictions	Infectious Disease or tuberculosis (TB) specialist
Coverage Duration	24 weeks
Other Criteria	N/A

# SKYCLARYS

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## Products Affected

- Skyclarys

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of Friedreich's ataxia (FA or FRDA) confirmed by genetic testing. Renewal: medical record documentation of a slowing of progression or clinical benefit.
Age Restrictions	Age at least 16 years or older
Prescriber Restrictions	Prescribed by, or in consultation with a neurologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# SKYRIZI

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 600MG/10ML
- Skyrizi Pen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Plaque psoriasis (PsO) initial: involvement of at least 3% of body surface area or hand, foot, face, scalp, or genital involvement. PsO renewal: improvement in affected body surface area, plaque severity and/or functioning. 2) Psoriatic arthritis (PsA) renewal: improved functioning and/or greater improvement in tender joint count and swollen joint count. C) Crohn's disease (CD) renewal criteria: a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. 4) Ulcerative colitis (UC) renewal: medical record documentation of treatment response such as decrease in bloody stools per day, elimination of signs of toxicity, or clinical remission.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with 1) a dermatologist for PsO, 2) dermatologist or rheumatologist for PsA. CD or UC: Prescribed by, or in consultation with a gastroenterologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Plaque psoriasis, initial: failure of 1) one topical agent such as a corticosteroid (i.e. betamethasone or clobetasol), calcipotriene, tazarotene (requires prior authorization), or tacrolimus and 2) methotrexate or cyclosporine.

## SOFOSBUVIR/VELPATASVIR

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### Products Affected

- Epclusa PACK
- Epclusa TABS 200MG; 50MG
- Sofosbuvir/velpatasvir

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Detectable HCV RNA (viral load), 2) Documentation of treatment history including response to previous treatment (treatment naïve, previous relapser, partial responder or null responder), and 3) Documentation of presence or absence of cirrhosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

# SOHONOS

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## Products Affected

- Sohonos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Medical record documentation of a diagnosis of fibrodysplasia ossificans progressiva (FOP), confirmed by ACVR1 R206H mutation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# SOLTAMOX

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## Products Affected

- Soltamox

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concomitant coumarin-type anticoagulant therapy or in women with a history of deep vein thrombosis or pulmonary embolus.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Documentation of an inability to take solid oral dosage forms.

# SOMATROPINS

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## Products Affected

- Genotropin
- Genotropin Miniquick
- Humatrope INJ 12MG, 24MG, 6MG
- Norditropin Flexpro
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Omnitrope
- Saizen
- Saizenprep Reconstitutionkit
- Zorbtive

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	1) In patients with Prader-Willi syndrome, patients who are severely obese, have a history of upper airway obstruction, sleep apnea or severe respiratory impairment. 2) Not approved for the treatment of acute critical illness, respiratory failure or patients with an underlying intracranial tumor.
<b>Required Medical Information</b>	1) Growth Hormone Deficiency (GHD): a) short stature (SS) defined by one of the following:(i) height more than 3 standard deviations (SD) below mean for age and gender or (ii) height below the 3rd percentile for age and gender or (iii) height more than 2 SD below mean and growth velocity (GV) below the 25th percentile for age and gender or (iv) growth velocity less than 2 SD below the mean for age and gender AND b) laboratory results consistent with growth hormone deficiency. 2) Idiopathic SS: short stature as defined under GHD. 3) Prader-Willi syndrome: confirmed by genetic testing or decreased muscle tone by exam. 4) Turner's Syndrome and short-stature homeobox-containing gene (SHOX) deficiency: confirmation of diagnosis by genetic testing. 5) Small for gestational age (SGA) with no catch-up growth by age 2 to 4 years: height remains less than 2 SD below the mean for age and gender. 6) Adult-Onset GHD: a) Pituitary, hypothalamic disease, or GHD as a result of tumor, irradiation, surgery or trauma AND b) laboratory results consistent with growth hormone deficiency. 7) Childhood-Onset Adult GHD: a) laboratory results consistent with growth hormone deficiency. Renewal for all: documentation of improved quality of life or clinical benefit.
<b>Age Restrictions</b>	SBS: Age at least 18 years
<b>Prescriber Restrictions</b>	Endocrinologist, Gastroenterologist, or Nephrologist
<b>Coverage Duration</b>	SBS: 4 weeks. All other diagnoses: 12 months.
<b>Other Criteria</b>	N/A

# SOMATULINE DEPOT

## Products Affected

- Lanreotide Acetate
- Somatuline Depot

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	1) For the treatment of acromegaly and Carcinoid Syndrome: failure of octreotide or reason why octreotide cannot be used. 2) The following criteria applies to members who newly start on the drug for gastroenteropancreatic neuroendocrine tumors: failure of octreotide or reason why octreotide cannot be used.

# SOMAVERT

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## Products Affected

- Somavert

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Baseline liver function tests are not greater than 3 times the upper limit of normal.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# SOTYLIZE

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## Products Affected

- Sotylyze

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Medical record documentation of an inability to take solid oral dosage forms.

# SPRAVATO

## Products Affected

- Spravato 56mg Dose
- Spravato 84mg Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The following criteria applies to members who newly start on the drug: 1) For treatment resistant major depressive disorder: medical record documentation of failure of separate 6 week trials of two different antidepressants . 2) For treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior: documentation that Spravato will be used in conjunction with an oral antidepressant.
Age Restrictions	N/A
Prescriber Restrictions	Psychiatrist
Coverage Duration	Lifetime
Other Criteria	N/A

# SPRITAM

## Products Affected

- Levetiracetam TB3D
- Spritam TB3D 1000MG, 500MG, 750MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Evidence from documentation or claims history that Spritam is not being used as monotherapy for myoclonic seizures or primary generalized tonic-clonic seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime.
Other Criteria	<p>The following criteria applies to members who newly start on the drug: 1) For the treatment of partial-onset seizures, failure of the following: a) levetiracetam tablets or oral solution and b) one of the following: carbamazepine tablet/chew tablet/suspension, oxcarbazepine tablet/suspension, phenytoin capsule/chew tablet/suspension, topiramate, divalproex, felbamate tablet/suspension, tiagabine, lamotrigine tablet/chew tablet/oral disintegrating tablet, gabapentin tablet/capsule/solution, lacosamide tablet/suspension or zonisamide. 2) For the treatment of primary generalized tonic-clonic seizures, failure of the following: a) levetiracetam tablets or oral solution and b) one of the following: topiramate, lamotrigine tablet/chew tablet/oral disintegrating tablet, phenytoin capsule/chew tablet/suspension, lacosamide tablet/suspension or carbamazepine tablet/chew tablet/suspension. 3) For the treatment of myoclonic seizures. failure of the following: a) levetiracetam tablets or oral solution and b) one of the following: divalproex, lamotrigine tablet/chew tablet/oral disintegrating tablet or topiramate.</p>

# STAMARIL

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## Products Affected

- Stamaril

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of planned travel to a country at risk for yellow fever. Renewal: Documentation that it has been at least 10 years since the previous dose, or that a booster is recommended to travel to a specific country.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month for 1 dose
Other Criteria	N/A

# STRENSIQ

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## Products Affected

- Strensiq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis confirmed by genetic testing, low serum activity of alkaline phosphatase or elevated pyridoxine.
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist, Geneticist or Metabolic Specialist
Coverage Duration	Lifetime
Other Criteria	N/A

# SUCRAID

## Products Affected

- Sucraid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Diagnosis confirmed by one of the following: a) acidic stool pH less than 6, b) increase in breath hydrogen of greater than 10 ppm when challenged with sucrose or c) genetic testing showing sucrase deficiency and 2) Objective, measurable treatment goals are provided. Renewal: medical record documentation of treatment response such as improvement in growth and development or decrease in diarrhea, flatulence or abdominal pain.
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist, Endocrinologist, Metabolic Specialist
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label: Weight greater than 15kg: 17,000 IU per meal or snack. Weight less than 15kg: 8,500 IU per meal or snack.

# SYMDEKO

## Products Affected

- Symdeko

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Medical record documentation of a diagnosis of cystic fibrosis homozygous for the F508del mutation or has a mutation that is responsive to the drug confirmed using an FDA-cleared cystic fibrosis mutation test. Renewal criteria: Medical record documentation of treatment response such as an improvement in FEV1, reduction in pulmonary exacerbation, or improvement in respiratory symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# SYMPAZAN

## Products Affected

- Sympazan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Sympazan must be used as adjunctive treatment.
Age Restrictions	Age at least two.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: 1) For Lennox-Gastaut, petit mal variant, failure of a) clonazepam and b) one of the following: valproate, topiramate, lamotrigine, felbamate or rufinamide. 2) For Lennox-Gastaut, other seizure types, failure of two of the following: clonazepam, valproate, topiramate, lamotrigine, felbamate or rufinamide. 3) For all indications, documentation of an inability to swallow solid and liquid dosage forms (tablets and suspension).

# SYMPROIC

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## Products Affected

- Symproic

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of fewer than 3 spontaneous bowel movements per week.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

# SYNAGIS

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## Products Affected

- Synagis INJ 100MG/ML,  
50MG/0.5ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Current age less than 12 months at the start of the RSV season and gestational age is less than 29 weeks and 0 days. 2) Preterm infants who develop chronic lung disease (CLD) of prematurity: a) gestational age is less than 32 weeks and 0 days gestation, b) greater than 21% oxygen requirement for at least 28 days and c) one of the following: current age less than 12 months or current age 12 to 24 months and there is continued need for supplemental oxygen, chronic corticosteroids, or diuretic therapy during the 6 month period prior to the start of the RSV season. 3) Current age less than 12 months with hemodynamically significant congenital heart disease and one of the following: a) acyanotic heart disease who is receiving medication to control CHF and will require cardiac surgical procedures or b) moderate to severe pulmonary hypertension. 4) Current age less than or equal to 12 months with congenital abnormalities of the airway or neuromuscular disease that impairs the ability to clear secretions from the upper airways. 5) Age less than 24 months who will be profoundly immunocompromised during RSV season (such as chemotherapy, or post solid organ or stem cell transplant.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Max of 5 doses
<b>Other Criteria</b>	For patients less than 24 months and with chronic lung disease or hemodynamically significant congenital heart disease, Synagis will be covered for a maximum of 2 seasons. The maximum number of doses depends on the diagnosis or for preterm infants based on gestational age. Synagis season typically starts on November 1st and ends March 31st. Requests are reviewed for November administration unless the CDC surveillance indicates that the season has started earlier. The season will be extended after March 31st until the CDC surveillance report for the region indicates the season is over. A maximum of 5 doses, 1 dose per month, will be approved during the RSV season unless gestational age is

	between 32 and 34 weeks and 6 days where Synagis will be approved until the patient reaches 90 days of age.
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# SYNAREL

## Products Affected

- Synarel

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (EM): requires laparoscopic confirmation of diagnosis.
Age Restrictions	Central precocious puberty: Female age less than 11 years, Male age less than 12 years. Endometriosis: age at least 18 years.
Prescriber Restrictions	EM: Prescribed by or in consultation with ob/gyn specialist or endocrinologist. Central precocious puberty: Prescribed by or in consultation with pediatric endocrinologist or endocrinologist.
Coverage Duration	Endometriosis: 6 months. Central precocious puberty: female until age 11 and male until age 12.
Other Criteria	N/A

# TADALAFIL

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## Products Affected

- Alyq
- Tadalafil TABS 20MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concurrent use of nitrates.
Required Medical Information	Documentation of New York Heart Association (NYHA) Class II or III.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	Lifetime
Other Criteria	N/A

# TADALAFIL BPH

## Products Affected

- Tadalafil TABS 5MG

PA Criteria	Criteria Details
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of a diagnosis of benign prostatic hyperplasia (BPH). Renewal: medical record documentation of an improvement in symptoms of BPH.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	Initial: failure of 1) an alpha blocker such as tamsulosin or alfuzosin and 2) an alpha reductase inhibitor such as finasteride or dutasteride.

# TADLIQ

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## Products Affected

- Tadliq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of an inability to swallow oral tablets or capsules.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a cardiologist or pulmonologist.
Coverage Duration	Lifetime
Other Criteria	N/A

# TAKHZYRO

## Products Affected

- Takhzyro

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Documentation of hereditary angioedema Type I and II confirmed by genetic testing or complement studies of C4, C1INH antigenic and C1INH functional levels supporting the diagnosis. For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history. Renewal criteria for long term prevention: Documentation of a reduction in the number of angioedema attacks, significant improvement in the severity and duration of attacks or clinical documentation of functional improvement.
Age Restrictions	Age at least 2 years.
Prescriber Restrictions	Hematologist, allergist or immunologist.
Coverage Duration	Long term prevention initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# TALTZ

## Products Affected

- Taltz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Plaque psoriasis (PsO) initial: involvement of at least 3% of body surface area or hand, foot, face, scalp, or genital involvement. PsO renewal: improvement in affected body surface area, plaque severity and/or functioning. 2) Psoriatic arthritis renewal: improvement in functioning and/or decreased in number of tender, swollen joints and reduction in skin lesions and/or has disease stability. 3) Ankylosing spondylitis (AS) renewal: improved functioning and/or signs and symptoms of AS. 4) active non-radiographic axial spondyloarthritis (axSPA) renewal: improved functioning and/or signs and symptoms of active non-radiographic axial spondyloarthritis.
Age Restrictions	N/A
Prescriber Restrictions	Plaque psoriasis: dermatologist. Psoriatic arthritis: dermatologist or rheumatologist. Ankylosing spondylitis, and axSPA: rheumatologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	PsA initial: failure of two of the following: Enbrel, adalimumab (Humira or adalimumab-adbm), Simponi, Orencia, Otezla, Cosentyx, Skyrizi, Stelara, Rinvoq, or Xeljanz (IR or XR). All require prior authorization. PsO initial: failure of two of the following: Enbrel, adalimumab (Humira or adalimumab-adbm), Otezla, Cosentyx, Skyrizi, or Stelara. All require prior authorization. AS initial: failure of two of the following: Enbrel, Humira or adalimumab-adbm, Simponi, Cosentyx, or Xeljanz (IR or XR). All require prior authorization. axSPA initial: failure of Cosentyx with prior authorization.

# TARPEYO

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## Products Affected

- Tarpeyo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of primary immunoglobulin A nephropathy at risk of rapid disease progression.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a nephrologist.
Coverage Duration	9 months
Other Criteria	Failure of or intolerance to prednisone.

# TAVALISSE

## Products Affected

- Tavalisse

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Medical record documentation of platelet count less than 20,000 per mm <sup>3</sup> or less than 30,000 per mm <sup>3</sup> with symptoms of bleeding. Renewal criteria: Medical record documentation of maintenance of platelet counts of at least 30,000 per mm <sup>3</sup> or an increase in platelet counts from baseline with resolution of bleeding episodes.
Age Restrictions	N/A
Prescriber Restrictions	Hematologist or Oncologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months
Other Criteria	For chronic immune (idiopathic) thrombocytopenia: documentation of an insufficient response to a previous treatment such as: steroids, IVIG, Promacta, or Rituxan.

# TAVNEOS

## Products Affected

- Tavneos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: documentation of microscopic polyangiitis or granulomatosis with polyangiitis, a positive test for anti-PR3 or anti-MPO, documentation that Tavneos will be used in combination with standard therapy (including corticosteroids), and at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS). Renewal: Documentation of clinical remission, improved BVAS score or improved functioning and/or symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a rheumatologist or nephrologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# TAZORAC

## Products Affected

- Tazarotene CREA 0.1%
- Tazarotene GEL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pregnancy
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	1) For acne vulgaris: documentation of failure of topical tretinoin. 2) For psoriasis vulgaris: documentation of failure of a mid-to-high potency topical corticosteroid (eg. triamcinolone, betamethasone, fluocinonide, or clobetasol) and topical calcipotriene.

# TEGSEDI

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## Products Affected

- Tegsedi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Transthyretin variant by genotyping, documented amyloid deposit by biopsy. Renewal criteria: medical record documentation of improvement in pain or functioning.
Age Restrictions	18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	N/A

# TERIFLUNOMIDE

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## Products Affected

- Teriflunomide

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Documentation that teriflunomide is being requested for monotherapy and is not intended to be used in combination with other multiple sclerosis agents.

# TERIPARATIDE

## Products Affected

- Teriparatide

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Patients at increased baseline risk for osteosarcoma (including those with Paget's disease of bone, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).
<b>Required Medical Information</b>	1) Postmenopausal female with either a) evidence of recent radiographic osteoporotic fracture while on a bisphosphonate or b) high risk or very high risk of osteoporotic fracture. 2) Male with primary or hypogonadal osteoporosis and either a) evidence of history of osteoporotic fracture or b) multiple risk factors for osteoporotic fractures such as BMD less than -2.5 SD, low BMI, history of hip fracture in 1st degree relative, tall stature, and chronic daily use of tobacco. 3) Female or male with steroid-induced osteoporosis and both: a) steroid use for greater than 3 months at a dose of 5mg per day prednisone (or equivalent) and b) BMD T-score less than -2.5. Renewal for all indications: for use longer than 2 years, documentation of high risk of fracture.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Failure of or contraindication to an oral bisphosphonate, unless considered very high risk for fracture.

# TESTOSTERONE-SYSTEMIC

## Products Affected

- Methitest

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Men with carcinoma of the breast. 2) Men with known or suspected carcinoma of the prostate.
Required Medical Information	1) For members newly started on the drug for the treatment of primary or secondary hypogonadism: a) total testosterone level less than 300 ng/dL or b) free testosterone level below the normal range for age and gender. 2) Delayed puberty: Skeletal age of at least 12 or chronological age of at least 14.
Age Restrictions	N/A
Prescriber Restrictions	For metastatic breast cancer: oncologist
Coverage Duration	Delayed puberty: 6 months. All other diagnoses: lifetime.
Other Criteria	For treatment of secondary hypogonadism: failure of testosterone cypionate and topical testosterone gel.

# TETRABENAZINE

## Products Affected

- Tetrabenazine

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications, Some Medically accepted Indications.
<b>Off-Label Uses</b>	1) Tardive dyskinesia and 2) Tourette's Syndrome.
<b>Exclusion Criteria</b>	1) Patients who are actively suicidal or with untreated or inadequately treated depression. 2) Patients with impaired hepatic function. 3) Patients taking monoamine oxidase inhibitors. 4) Patients taking reserpine. At least 20 days should elapse after stopping reserpine before starting tetrabenazine.
<b>Required Medical Information</b>	Initial criteria: If the request is for doses greater than 50 mg per day, medical record documentation of CYP2D6 genotyping is required. Renewal criteria: Medical record documentation of a clinical response such as improvement in chorea, ability to perform activities of daily living, reduction in falls, and increase in quality of life.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# THALOMID

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## Products Affected

- Thalomid

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Erythema Nodosum Leprosum (ENL) Renewal criteria: documentation of response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	MM: Oncologist or Hematologist. ENL: Dermatologist. Infectious Disease: Infectious Disease Specialist
Coverage Duration	Cancer: Lifetime. ENL: 12 months.
Other Criteria	N/A

# TICOVAC

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## Products Affected

- Ticovac

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of planned travel to an endemic country. Renewal for fourth dose: documentation of continued risk after 3 years from initial doses.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 12 months. Renewal: 1 month.
Other Criteria	N/A

# TIGECYCLINE

## Products Affected

- Tigecycline

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Complicated infection of skin and/or subcutaneous tissue: Culture and sensitivity indicates resistance to vancomycin plus aztreonam. 2) Complicated infectious disease of abdomen: Culture and sensitivity indicates resistance to imipenem/cilastin. 3) Community acquired pneumonia: a) Severity of infection necessitates IV treatment and a) Culture and sensitivity indicates resistance to i) a beta-lactam, such as cefotaxime, ceftriaxone plus azithromycin or clarithromycin and ii) fluoroquinolone such as levofloxacin or moxifloxacin.
Age Restrictions	Age at least 18 years
Prescriber Restrictions	Infectious disease specialist
Coverage Duration	14 days
Other Criteria	N/A

# TIROSINT SOLUTION

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## Products Affected

- Tirosint-sol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Documentation of an inability to take solid oral dosage forms.

# TOPICAL ANTIVIRALS

## Products Affected

- Acyclovir CREA
- Acyclovir OINT
- Penciclovir CREA

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	1) Applies to acyclovir ointment only: for genital herpes or patient who are immunocompromised with non-life-threatening mucocutaneous herpes simplex infection, failure of oral acyclovir. 2) For penciclovir: for recurrent herpes simplex labialis (oral herpes), failure of topical acyclovir cream.

# TREPROSTINIL

## Products Affected

- Treprostinil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of New York Heart Association (NYHA) Class II to IV.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist or Cardiologist
Coverage Duration	Lifetime
Other Criteria	Failure of or contraindication to 1) sildenafil or tadalafil and 2) bosentan or ambrisentan. All require prior authorization.

# TRIKAFTA

## Products Affected

- Trikafta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Medical record documentation of a diagnosis of cystic fibrosis with at least one F508del mutation or has a mutation that is responsive to the drug confirmed using an FDA-cleared cystic fibrosis mutation test. Renewal criteria: Medical record documentation of treatment response such as an improvement in FEV1, reduction in pulmonary exacerbation, or improvement in respiratory symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# TRINTELLIX

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## Products Affected

- Trintellix

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Failure of 1) a selective serotonin reuptake inhibitor (SSRI): such as fluoxetine, paroxetine, citalopram, escitalopram, sertraline, AND 2) venlafaxine or duloxetine.

# TRULICITY

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## Products Affected

- Trulicity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of type 2 diabetes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# TRUMENBA

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## Products Affected

- Trumenba

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age 10-25 years
Prescriber Restrictions	N/A
Coverage Duration	Series of 3 doses in 6 months.
Other Criteria	N/A

# TRYNGOLZA

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## Products Affected

- Tryngolza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Documentation of a diagnosis of Familial Chylomicronemia Syndrome (FCS) confirmed by a genetic test. Renewal: 1) a reduction in triglycerides from baseline, and 2) documentation of clinical improvement such as episodes of acute pancreatitis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a lipid specialist, endocrinologist, cardiologist, gastroenterologist, or pancreatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# TRYVIO

## Products Affected

- Tryvio

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Medical record documentation of 1) blood pressure that is not adequately controlled on multiple blood pressure lowering medications and 2) that Tryvio will be prescribed in combination with other blood pressure lowering medications. Renewal: documentation of reduction in blood pressure from baseline.
<b>Age Restrictions</b>	Age of at least 18 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist, nephrologist or endocrinologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Initial: Failure of at least two of the following: 1) a beta blocker such as metoprolol, carvedilol, atenolol, 2) a calcium channel blocker such as amlodipine, nifedipine, diltiazem, verapamil, 3) an angiotensin receptor blocker or ACE inhibitor such as losartan or lisinopril, 4) a diuretic such as hydrochlorothiazide.

# TYMLOS

## Products Affected

- Tymlos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton).
Required Medical Information	1) For Postmenopausal females: a) evidence of recent radiographic osteoporotic fracture while on a bisphosphonate or b) high risk or very high risk of osteoporotic fracture. 2) For males: a) documentation of high risk of fracture or b) failure of or intolerance to other osteoporosis therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 months. Use is not recommended for longer.
Other Criteria	1) Failure of or contraindication to an oral bisphosphonate, unless considered very high risk for fracture. 2) If there is prior history of a parathyroid hormone analog, cumulative use is not greater than 2 years. If there is prior history then coverage will be allowed to provide a maximum of 24 months of treatment during a lifetime.

# TYSABRI

## Products Affected

- Tysabri

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	History of or existing progressive multifocal leukoencephalopathy.
Required Medical Information	Crohn's disease: 1) Baseline CRP greater than 2.87mg/L and 2) if the patient is currently on oral corticosteroids, requires documentation of a steroid taper plan. Renewal criteria for Crohn's disease: documentation of a) reduction in CDAI or number of disease flares and/or improved quality of life, b) If previously on oral steroids, steroid has been successfully discontinued, and c) no history of serious infection or evidence of liver toxicity since the previous authorization. MS renewal: documented benefit since initiation of Tysabri such as delay in the accumulation of physical disability and/or reduction in the frequency of clinical exacerbations and no symptoms suggestive of PML (e.g. progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes).
Age Restrictions	Age at least 18 years
Prescriber Restrictions	Neurologist or gastroenterologist
Coverage Duration	12 months
Other Criteria	1) 2) Crohn's disease: failure of infliximab and Humira. 2) Multiple sclerosis: failure of interferon-beta (Avonex, Rebif, Betaseron), Copaxone, Gilenya or Tecfidera with documentation of all of the following a) continuation of clinical relapses b) CNS lesion progression on MRI or worsening disability and c) not on combination therapy with Avonex, Rebif, Betaseron, Copaxone, Glatopa, Extavia, Gilenya or Tecfidera.

# UBRELVY

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## Products Affected

- Ubrelvy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Failure of two triptans such as eletriptan, sumatriptan, naratriptan, rizatriptan, or zolmitriptan. If triptans are contraindicated: failure of 1) naproxen and 2) one other NSAID such as ibuprofen, diclofenac, flurbiprofen or celecoxib.

# USTEKINUMAB

## Products Affected

- Steqeyma
- Wezlana

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Psoriasis with arthropathy (PsA) renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 2) Plaque psoriasis (PsO) initial: involvement of at least 3% of body surface area or hand, foot, face, scalp, or genital involvement.) PsO renewal: improvement in affected body surface area, plaque severity and/or functioning. 3) Crohn's Disease (CD) renewal: medical record documentation of a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission. 4) Ulcerative colitis (UC) renewal: medical record documentation of treatment response such as decrease in bloody stools per day, elimination of signs of toxicity, and/or clinical remission.
Age Restrictions	N/A
Prescriber Restrictions	Psoriatic arthritis: rheumatologist or dermatologist. Plaque psoriasis: dermatologist. Crohn's Disease and Ulcerative Colitis: gastroenterologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Plaque psoriasis, initial criteria: failure of 1) one topical agent such as a corticosteroid (i.e. betamethasone or clobetasol), calcipotriene, tazarotene (requires prior authorization), or tacrolimus (requires prior authorization) and 2) methotrexate or cyclosporine.

# UZEDY

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## Products Affected

- Uzedy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: failure of risperidone intramuscular injection (generic Risperdal Consta).

# VARIZIG

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## Products Affected

- Varizig INJ 125UNIT/1.2ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

# VAXCHORA

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## Products Affected

- Vaxchora

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Medical record documentation of a plan to travel to a cholera-affected area.
Age Restrictions	Age 2 through 64 years of age.
Prescriber Restrictions	N/A
Coverage Duration	1 month for 1 dose
Other Criteria	N/A

# VELTASSA

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## Products Affected

- Veltassa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: medical lab documentation of hyperkalemia. Renewal criteria: reduction in serum potassium from baseline.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# VENTAVIS

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## Products Affected

- Ventavis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of New York Heart Association (NYHA) Class III to IV.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist or cardiologist
Coverage Duration	Lifetime
Other Criteria	Failure of or contraindication to 1) sildenafil or tadalafil and 2) bosentan or ambrisentan. All require prior authorization.

# VEOZAH

## Products Affected

- Veozah

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of moderate to severe vasomotor symptoms due to menopause. Renewal: documentation of a reduction in severity of vasomotor symptoms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	1) Failure of paroxetine. 2) Failure of, or contraindication to estradiol.

# VERKAZIA

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## Products Affected

- Verkazia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: documentation of an improvement in symptoms of vernal keratoconjunctivitis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# VERQUVO

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## Products Affected

- Verquvo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of 1) ejection fraction of less than 45%, 2) NYHA class II-IV, 3) a recent decompensation requiring hospitalization or a need for outpatient IV diuretics.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	Lifetime
Other Criteria	N/A

# VERSACLOZ

## Products Affected

- Versacloz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Documentation of an inability to use clozapine oral disintegrating tablets.

## VESICARE LS

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### Products Affected

- Vesicare Ls

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of neurogenic detrusor overactivity.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# VIBERZI

## Products Affected

- Viberzi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic drinks daily. 2) Known or suspected biliary duct obstruction. 3) History of or current chronic or severe constipation. 4) Severe hepatic impairment. 5) Known or suspected mechanical gastrointestinal obstruction. 6) History of pancreatitis. 7) Sphincter of Oddi disease or dysfunction. 8) Structural disease of the pancreas such as pancreatic duct obstruction.
Required Medical Information	Initial: Medical record documentation of irritable bowel syndrome with diarrhea. Documented symptoms of loose or watery stools at least greater than or equal to 25% of stools. Renewal: Medical record documentation of a significant reduction in diarrhea frequency and abdominal pain and/or improvement in quality of life during the 12 week trial.
Age Restrictions	Age at least 18 years
Prescriber Restrictions	N/A
Coverage Duration	Initial: 12 weeks. Renewal: Lifetime.
Other Criteria	Failure of loperamide and dicyclomine.

# VIGABATRIN

## Products Affected

- Vigabatrin
- Vigadrone
- Vigafyde
- Vigpoder

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Complex Partial Seizures (CPS) Initial: Requires use with another anticonvulsant as combination therapy.
Age Restrictions	Infantile Spasm: age less than 2 years
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug for the treatment of Complex Partial Seizures: Failure of adjunctive treatment with at least two of the following: topiramate, felbamate, gabapentin, lamotrigine, tiagabine, levetiracetam, oxcarbazepine, zonisamide or lacosamide.

# VIIBRYD

## Products Affected

- Viibryd Starter Pack
- Vilazodone Hydrochloride

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concomitant use of a MAOI or within 14 days after discontinuing a MAOI.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Documentation of failure of 1) a selective serotonin reuptake inhibitor such as paroxetine, fluoxetine, citalopram, escitalopram or sertraline and 2) venlafaxine or duloxetine.

# VIJOICE

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## Products Affected

- Vioice

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: a) medical record documentation of a mutation in the PIK3CA gene. b) documentation of the need for systemic therapy. Renewal: documentation of a reduction in lesion size or significant improvement in symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a genetic specialist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# VORICONAZOLE

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## Products Affected

- Voriconazole INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Until end of plan year
Other Criteria	N/A

# VOSEVI

## Products Affected

- Vosevi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Detectable HCV RNA (viral load), 2) Documentation of treatment history including response to previous treatment (treatment naïve, previous relapser, partial responder or null responder) with a NS5A inhibitor for genotype 1 to 6 and/or sofosbuvir without an NS5A inhibitor for genotype 1a and genotype 3 and 3) Documentation of presence or absence of cirrhosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance
Other Criteria	N/A

# VOWST

## Products Affected

- Vowst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	1) Documentation of at least 1 recurrent episode of c. difficile infection (CDI) with a positive stool test and 2) documentation that Vowst will be initiated within 2-4 days following completion of an antibiotic course of treatment for CDI.
Age Restrictions	At least 18 years of age.
Prescriber Restrictions	N/A
Coverage Duration	3 days
Other Criteria	N/A

# VOXZOGO

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## Products Affected

- Voxzogo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) diagnosis of achondroplasia confirmed by genetic testing with a mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, and 2) open epiphyses. Renewal: medical record documentation of open epiphyses.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an endocrinologist.
Coverage Duration	12 months
Other Criteria	N/A

# VOYDEYA

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## Products Affected

- Voydeya

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: confirmation of a diagnosis of paroxysmal nocturnal hemoglobinuria via flow cytometry. Renewal criteria: medical record documentation of clinical benefit, such as increase in hemoglobin level from baseline.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with a hematologist or an oncologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

## VPRIV

### Products Affected

- Vpriv

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Diagnosis confirmed by one of the following: a) biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts is less than or equal to 30% of normal activity, b) genotyping revealing 2 pathogenic mutations of the glucocerebrosidase gene. 2) Severity of disease results in one or more of the following conditions: a) moderate to severe anemia, b) thrombocytopenia with bleeding tendency, c) bone disease, d) significant hepatomegaly or splenomegaly. 3) Objective, measurable treatment goals are provided. Renewal: 1) Medical record documentation of stabilization of disease progression, such as a) improvement in hematologic markers, such as increased hgb/hct and/or platelet counts, b) reduction in spleen or liver volume, c) reduction in biochemical markers, such as chitotrisidase, ACE, acid phosphatase tartrate resistant (TRAP), d) reduction in skeletal markers, such as DEXA scan, bone pain, bone age (for patient age 14 years or less).
Age Restrictions	Age 4 years and older
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Dosing consistent with product label: 60 units/kg every other week. Range 15-60 units/kg.

## VYND AQEL

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### Products Affected

- Vyndamax
- Vyndaqel

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation confirming the diagnosis of either wild-type or hereditary transthyretin amyloid cardiomyopathy (ATTRwt-CM or hATTR-CM).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	Lifetime
Other Criteria	N/A

## WAINUA

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### Products Affected

- Wainua

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: medical record documentation of genetic mutation in the TTR gene and Stage 1 or 2 familial amyloid polyneuropathy (FAP). Renewal: documentation of improvement in pain or functioning.
Age Restrictions	Age at least 18 years old.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Initial: 6 months. Renewal: Lifetime.
Other Criteria	N/A

# WAKIX

## Products Affected

- Wakix

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal criteria: medical record documentation of a significant improvement in daytime sleepiness and functioning.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: Lifetime.
Other Criteria	Narcolepsy, excessive daytime sleepiness (not required for narcolepsy/cataplexy): Failure of or intolerance to: 1) methylphenidate, dextroamphetamine or amphetamine/dextroamphetamine, AND 2) modafinil (requires PA).

# WEGOVY

## Products Affected

- Wegovy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For reducing the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease, initial: 1) Medical record documentation of established cardiovascular disease (such as prior stroke, myocardial infarction, or peripheral arterial disease). 2) Body mass index of at least 25 kg/m2.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Not covered for treatment of diabetes. Covered options for type 2 diabetes include Ozempic, Mounjaro, Trulicity, Victoza, Byetta and Bydureon, and Rybelsus (all require PA).

# WINREVAIR

## Products Affected

- Winrevair

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Documentation of WHO Group 1 pulmonary arterial hypertension diagnosed by right heart catheterization. Renewal: Documentation of clinical improvement or disease stability such as increased exercise capacity, improvement in WHO functional class, or decreased clinical worsening events.
Age Restrictions	At least 18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	Initial: 12 months. Renewal: Lifetime.
Other Criteria	Trial of, or contraindication to: 1) sildenafil or tadalafil and 2) bosentan, ambrisentan or macitentan. All require prior authorization.

# XARELTO SUSPENSION

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## Products Affected

- Xarelto SUSR

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Documentation of an inability to swallow oral tablets.

# XCOPRI

## Products Affected

- Xcopri

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: Failure of two of the following: carbamazepine, oxcarbazepine, phenytoin, topiramate, divalproex, felbamate, tiagabine, lamotrigine, gabapentin, zonisamide, lacosamide and levetiracetam.

# XDEM VY

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## Products Affected

- Xdemvy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record confirmation of blepharitis caused by demodex mites.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist.
Coverage Duration	6 weeks
Other Criteria	N/A

# XELJANZ

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## Products Affected

- Xeljanz
- Xeljanz Xr

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Rheumatoid arthritis (RA) initial: documentation of an inadequate response or intolerance to one or more TNF inhibitors (such as Humira, Enbrel, or Simponi). RA renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 2) Psoriasis with arthropathy (PsA) initial: documentation of an inadequate response or intolerance to one or more TNF inhibitor (such as Humira, Enbrel, or Simponi). PsA renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 3) Ulcerative Colitis (UC) initial: documentation of an inadequate response or intolerance to one or more TNF inhibitor (such as Humira or Simponi). UC renewal: medical record documentation of treatment response such as decrease in bloody stools per day, elimination of signs of toxicity, or clinical remission. 4) Active polyarticular course juvenile idiopathic arthritis (pcJIA) initial: documentation of an inadequate response or intolerance to one or more TNF inhibitor (such as Humira, Enbrel, or Simponi). pcJIA renewal: improved functioning and/or improvement in tender joint count and swollen joint count. 5) Ankylosing spondylitis (AS) initial: documentation of an inadequate response or intolerance to one or more TNF inhibitor (such as Humira, Enbrel, or Simponi). AS renewal: improvement in functioning and/or improvement in signs and symptoms of AS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Psoriatic arthritis: dermatologist or rheumatologist. Rheumatoid arthritis, juvenile idiopathic arthritis and ankylosing spondylitis: rheumatologist. Ulcerative colitis: gastroenterologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	RA initial: failure of methotrexate and at least one other DMARD such as leflunomide, sulfasalazine or hydroxychloroquine. AS initial: failure of one oral nonsteroidal anti-inflammatory drug such as meloxicam, ibuprofen, naproxen or diclofenac. pcJIA initial: failure of an 8 week trial of methotrexate. For oral solution only: documentation of an inability to swallow solid oral dosage forms, or documentation that the tablets are not indicated for the member's age.

# XENLETA

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## Products Affected

- Xenleta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of culture and susceptibility of pathogen.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	MRSA: 10 days. Non-MRSA: 5 days.
Other Criteria	Documentation of allergy to, drug interaction to or drug resistance to two of the following: 1) linezolid and 2) moxifloxacin or levofloxacin.

# XERMELO

## Products Affected

- Xermelo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial Criteria: 1) Carcinoid syndrome with 4 or more daily bowel movements despite the use of a somatostatin analog such as octreotide for at least 3 months and 2) concurrent use of a somatostatin analog. Renewal Criteria: Documentation of clinical response to therapy defined as a reduction from baseline in bowel movement frequency.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	N/A

# XGEVA

## Products Affected

- Xgeva

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Preexisting hypocalcemia and pregnancy.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	1) For bone metastasis associated with solid tumors and prevention of skeletal related events in patients with multiple myeloma: documentation of failure of zoledronic acid or there is a contraindication to zoledronic acid that is not a contraindication to denosumab. 2) For the treatment of hypercalcemia of malignancy: failure of one IV bisphosphonate including zoledronic acid or pamidronate.

# XOLAIR

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## Products Affected

- Xolair

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) For the treatment of allergic asthma: Initial: a) Positive skin prick test or in-vitro specific IgE test (such as RAST, MAST, FAST, ELISA) to one or more perennial allergens, b) Total serum IgE of 30 -1,300 IU/mL for pediatric patients age 6-12 or 30 -700 IU/ml for age 12 and above, c) Documentation supporting poor asthma control such as multiple asthma exacerbations resulting in repeated uses of health care services including urgent care, ED visits or hospitalizations and/or limitation in activities of daily living. Renewal: Documentation of a reduction in asthma exacerbations and frequency of office visits, ED or urgent care visits, hospitalizations and in the use/need for oral steroids and sustained clinical improvement from baseline. 2) For the treatment of chronic idiopathic urticaria: Initial: medical record documentation of urticaria for 6 weeks or longer. Renewal: documentation of clinical response to Xolair. 3) For the treatment of nasal polyps: Initial: a) documentation that Xolair is being used as add-on therapy, and b) documentation of an inadequate response to nasal corticosteroids. Renewal: Documentation of clinical benefit from Xolair. 4) For the treatment of IgE-mediated food allergy: initial: medical documentation of: a) IgE-mediate food allergy, b) allergic reaction to one more foods, and c) that Xolair will be used in conjunction with food allergen avoidance. Renewal: That Xolair continues to be used in conjunction with food allergen avoidance.
<b>Age Restrictions</b>	For chronic idiopathic urticaria: age at least 12 years. For allergic asthma, age at least 6 years.
<b>Prescriber Restrictions</b>	For allergic asthma: Pulmonologist or Immunologist. For chronic idiopathic urticaria: Allergist, Immunologist or Dermatologist. For IgE-mediated food allergy: Allergist or Immunologist.
<b>Coverage Duration</b>	Initial, all: 12 weeks. Renewal: asthma, nasal polyps, IgE allergy: 6 months. Urticaria: lifetime.
<b>Other Criteria</b>	1) For the treatment of allergic asthma: failure of, intolerance to or contraindication to a high-dose inhaled corticosteroid and a long-acting beta agonist. 2) For the treatment of chronic idiopathic urticaria: failure of, intolerance to or contraindication to two formulary antihistamines for

	at least two weeks (failure defined as continued hives and itching). Formulary antihistamines include levocetirizine and desloratadine.
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# XOLREMDI

## Products Affected

- Xolremdi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) medical record documentation of a diagnosis of warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome, confirmed by molecular genetic testing or a bone marrow biopsy. 2) baseline absolute neutrophil count and absolute lymphocyte count. Renewal: medical record documentation of an increase in absolute neutrophil count and absolute lymphocyte count from baseline.
Age Restrictions	Age of at least 12 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, immunologist or dermatologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months
Other Criteria	N/A

# XURIDEN

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## Products Affected

- Xuriden

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Genetic testing indicating a deficiency in uridine 5'-monophosphate (UMP) synthase or above normal urine concentration of orotic acid. Renewal: evidence of hematologic improvements.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation of a endocrinologist or a metabolic specialist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

# XYREM

## Products Affected

- Sodium Oxybate
- Xyrem

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	1) Succinic semialdehyde dehydrogenase deficiency. 2) Concurrent treatment with sedative hypnotics.
Required Medical Information	Renewal criteria: medical record documentation of a significant improvement in daytime sleepiness and functioning.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: Lifetime.
Other Criteria	Narcolepsy, excessive daytime sleepiness (not required for narcolepsy/cataplexy): Failure 1) modafinil and 2) one of the following: methylphenidate, amphetamine-dextroamphetamine, or dextroamphetamine.

# XYWAV

## Products Affected

- Xywav

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renewal: Medical record documentation of a significant improvement in daytime sleepiness and functioning.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Renewal: Lifetime.
Other Criteria	Narcolepsy, excessive daytime sleepiness (not required for narcolepsy/cataplexy or idiopathic hypersomnia): Failure of or intolerance to: 1) methylphenidate, dextroamphetamine or amphetamine/dextroamphetamine, AND 2) modafinil (requires PA).

# YORVIPATH

## Products Affected

- Yorvipath

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial criteria: Prior to initiation of therapy, 25-hydroxyvitamin D stores is within normal range and serum calcium (albumin adjusted) greater than or equal to 7.8 mg/dL. Renewal criteria: maintenance of serum calcium (albumin-corrected) concentration in the low-normal range.
Age Restrictions	Age at least 18 years
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or nephrologist
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	N/A

## ZAVESCA

### Products Affected

- Miglustat
- Yargesa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Diagnostic conformation by biochemical assay of decreased glucocerebrosidase activity in WBCs or skin fibroblasts, or genotyping revealing two pathogenic mutations of the glucocerebrosidase gene, and 2) Hgb at least 9g/dL and platelet at least 50 x109/L, and 3) Patient is unable to use enzyme replacement therapy due to allergy or poor venous access. Renewal: Medical record documentation of stabilization of disease progression such as 1) Improvement in hematologic markers such as increased Hgb/Hct and/or platelet counts or 2) Reduction in spleen or liver volume, or biochemical markers, such as chitotrisidase, ACE, acid phosphatase tartrate resistant (TRAP), or skeletal markers, such as DEXA scan, bone pain.
Age Restrictions	Age at least 18 years.
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Dosing consistent with product label: 100mg up to three times a day.

## ZEMAIRA/PROLASTIN

### Products Affected

- Prolastin-c
- Zemaira

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) documented ZZ or Z/null AAT deficiency and 2) AAT serum level less than or equal to 11 micromoles/L or 50mg/dL and 3) moderate emphysema and/or FEV1 less than 80% and 4) the provider has outlined specific, measurable treatment goals such as slowing of FEV1 decline or lack of disease progression. Renewal: documentation patient is meeting treatment goals such as slowing FEV1 decline or lack of disease progression.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist
Coverage Duration	Initial: 3 months. Renewal: 12 months.
Other Criteria	Initial: Medical record documentation of failure of or intolerance to Aralast or reason why Aralast cannot be used.

## ZEPBOUND

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### Products Affected

- Zepbound

PA Criteria	Criteria Details
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: 1) Medical record documentation of moderate to severe sleep apnea confirmed by polysomnography. 2) BMI of greater than or equal to 30kg/m2.
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

# ZILBRYSQ

## Products Affected

- Zilbrysq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record confirmation of a diagnosis of generalized myasthenia gravis (gMG) and anti-acetylcholine receptor (AChR) antibody positive status. Renewal: medical record documentation of a clinical response, such as improvement in function.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Initial: 6 months. Renewal: 12 months.
Other Criteria	Failure of 1) pyridostigmine, and 2) an immunomodulator such as azathioprine, mycophenolate or cyclosporine.

## ZINPLAVA

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### Products Affected

- Zinplava

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Evidence that the patient is currently using standard antibacterial drug treatment according to the FDA approved label.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 dose per 180 days
Other Criteria	N/A

# ZOKINVY

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## Products Affected

- Zokinvy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medical record documentation of a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS), or processing-deficient progeroid laminopathies (PLs) confirmed by genetic testing.
Age Restrictions	N/A
Prescriber Restrictions	Specialist in genetics or metabolic disorders
Coverage Duration	12 months
Other Criteria	N/A

## ZONISADE

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### Products Affected

- Zonisade

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria applies to members who newly start on the drug: documentation of an inability to take solid oral dosage forms.

## ZTALMY

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### Products Affected

- Ztalmy

PA Criteria	Criteria Details
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The following criteria applies to members who newly start on the drug: Medical record documentation confirming a diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

## ZURZUVAE

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### Products Affected

- Zurzuvae

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Current pregnancy.
Required Medical Information	Medical record documentation of a diagnosis of postpartum depression.
Age Restrictions	At least 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	14 days
Other Criteria	N/A

## ZYPREXA RELPREVV

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### Products Affected

- Zyprexa Relprevv

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The following criteria applies to members who newly start on the drug: currently taking oral olanzapine and prescriber wishes to switch to the injection to improve compliance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%,  
0.63MG/3ML, 1.25MG/3ML,  
2.5MG/0.5ML
- Aminosyn II INJ 993MG/100ML;  
1018MG/100ML; 700MG/100ML;  
738MG/100ML; 500MG/100ML;  
300MG/100ML; 660MG/100ML;  
1000MG/100ML; 1050MG/100ML;  
172MG/100ML; 270MG/100ML;  
298MG/100ML; 722MG/100ML;  
530MG/100ML; 400MG/100ML;  
200MG/100ML; 500MG/100ML
- Aminosyn-pf 7% INJ 32.5MEQ/L;  
490MG/100ML; 861MG/100ML;  
370MG/100ML; 576MG/100ML;  
270MG/100ML; 220MG/100ML;  
534MG/100ML; 831MG/100ML;  
475MG/100ML; 125MG/100ML;  
300MG/100ML; 570MG/100ML;  
347MG/100ML; 50MG/100ML;  
360MG/100ML; 125MG/100ML;  
44MG/100ML; 452MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Arformoterol Tartrate
- Azathioprine INJ
- Azathioprine TABS
- Bleomycin Sulfate INJ 30UNIT
- Budesonide SUSP
- Cladribine
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%

- Clinimix E 2.75%/dextrose 5% INJ  
570MG/100ML; 316MG/100ML;  
33MG/100ML; 5GM/100ML;  
515MG/100ML; 132MG/100ML;  
165MG/100ML; 201MG/100ML;  
159MG/100ML; 51MG/100ML;  
110MG/100ML; 454MG/100ML;  
154MG/100ML; 261MG/100ML;  
187MG/100ML; 138MG/100ML;  
217MG/100ML; 112MG/100ML;  
116MG/100ML; 50MG/100ML;  
11MG/100ML; 160MG/100ML
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine Modified
- Cytarabine INJ 100MG/ML,  
20MG/ML
- Cytarabine Aqueous
- Depo-medrol INJ 20MG/ML
- Engerix-b
- Everolimus TABS 0.25MG, 0.5MG,  
0.75MG, 1MG
- Ganciclovir INJ 500MG
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Heplisav-b
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML
- Ipratropium Bromide INHALATION  
SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Jylamvo
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU  
0.31MG/3ML, 1.25MG/3ML
- Levalbuterol Hydrochloride
- Methylprednisolone TABS

- Methylprednisolone Sodium Succinate
- Methylprednisolone Sodiumsuccinate  
INJ 40MG
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil INJ
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Myhibbin
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride ORAL  
SOLN
- Ondansetron Hydrochloride TABS
- Ondansetron Odt TBDP 4MG, 8MG
- Plenamine INJ 147.4MEQ/L;  
2.17GM/100ML; 1.47GM/100ML;  
434MG/100ML; 749MG/100ML;  
1.04GM/100ML; 894MG/100ML;  
749MG/100ML; 1.04GM/100ML;  
1.18GM/100ML; 749MG/100ML;  
1.04GM/100ML; 894MG/100ML;  
592MG/100ML; 749MG/100ML;  
250MG/100ML; 39MG/100ML;  
960MG/100ML
- Prednisone SOLN
- Prednisone TABS 10MG, 1MG,  
2.5MG, 20MG, 50MG, 5MG
- Prehevbrio
- Premasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 356MG/100ML;  
390MG/100ML; 34MG/100ML;  
152MG/100ML
- Prograf PACK
- Prosol
- Pulmozyme SOLN 2.5MG/2.5ML
- Rabavert
- Recombivax Hb
- Sirolimus SOLN

- Sirolimus TABS
- Solu-medrol INJ 500MG
- Tacrolimus CAPS
- Tobramycin NEBU 300MG/5ML
- Travasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 500MG/100ML;  
356MG/100ML; 390MG/100ML;  
34MG/100ML; 152MG/100ML
- Trexall
- Trophamine INJ 0.54GM/100ML;  
1.2GM/100ML; 0.32GM/100ML; 0; 0;  
0.5GM/100ML; 0.36GM/100ML;  
0.48GM/100ML; 0.82GM/100ML;  
1.4GM/100ML; 1.2GM/100ML;  
0.34GM/100ML; 0.48GM/100ML;  
0.68GM/100ML; 0.38GM/100ML;  
5MEQ/L; 0.025GM/100ML;  
0.42GM/100ML; 0.2GM/100ML;  
0.24GM/100ML; 0.78GM/100ML
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ 1MG/ML
- Xatmep

## Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

# INDEX

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