

## ABILIFY MAINTENA

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### Products Affected

- Abilify Maintena

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Documentation of one of the following 1) Currently taking oral Abilify and prescriber wishes to switch to the injection to improve compliance or 2) Failure of or intolerance to Risperdal Consta.

# ACTHAR HP

## Products Affected

- H.p. Acthar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Use of Acthar HP intravenously. Acthar 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. Acthar is contraindicated in patients under the age of 2 with suspected congenital infections and for patients who also have adrenocortical insufficiency or adrenocortical hyperfunction.
Required Medical Information	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.
Age Restrictions	For infantile spasms: age less than 2 years.
Prescriber Restrictions	N/A
Coverage Duration	Infantile spasms: until two years of age. All others: 1 month.
Other Criteria	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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D and 1) refractory atopic dermatitis and 2) T-cell lymphoma.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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 National Comprehensive Cancer Network guidelines. 2. For the treatment of refractory atopic dermatitis, failure of two of the following: cyclosporine, methotrexate, or azathioprine or a reason why they are not appropriate.

# ADAGEN

## Products Affected

- Adagen

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Use as preparatory or support therapy for bone marrow transplantation. 2) Severe thrombocytopenia.
<b>Required Medical Information</b>	Initial: Medical record documentation of 1) Diagnostic confirmation by immunologic, imaging or genetic studies, and 2) Patient is not a candidate for or has failed bone marrow transplant, and 3) Objective, measurable treatment goals. Renewal: Medical record documentation of stabilization of disease progression, such as diminished frequency of opportunistic infections or fewer complications of infections.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Dosing consistent with product label: Initial dosing is 10 units/kg, 15 units/kg, and 20 units/kg IM for the 1st, 2nd and 3rd dose, respectively, every 7 days. Maintenance dosing is 20 units/kg/week, with incremental increases by 5 units/kg/week to a maximum single dose of 30 units/kg.

# ADCIRCA

## Products Affected

- Adcirca

- Tadalafil TABS 20MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use of nitrates.
<b>Required Medical Information</b>	Initial: 1) Cardiac catheterization: mean Pulmonary Artery Pressure (mPAP) of at least 25 mmHg at rest, pulmonary capillary wedge pressure (PCWP) of less than 16 mmHg at rest, and New York Heart Association (NYHA) Class II or III, 2) Specific and measurable goals to assess response, such as an increase in the 6 minute walk test, decrease in dyspnea fatigue rating and other symptoms, evidence of hemodynamic improvement such as a reduction in mPAP and PVR or lack of functional decline. Renewal: Pre-defined treatment goals are being met.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	Initial: 12 weeks. Renewal: 12 months.
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: : failure of, intolerance to or contraindication to sildenafil.

# ADEMPAS

## Products Affected

- Adempas

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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. Renewal criteria for both WHO Group 1 and 4, documentation of a response to treatment with one of the following: 1) An increase in the 6 minute walk test, 2) Decrease in dyspnea fatigue rating and other symptoms, 3) Evidence of hemodynamic improvement such as a reduction in mPAP and PVR, or 4) Lack of functional or hemodynamic deterioration.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or cardiologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	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.

# AIMOVIG

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## Products Affected

- Aimovig

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	1) Episodic Migraine prophylaxis: failure of propranolol and topiramate. 2) Chronic Migraine prophylaxis: failure of 1) propranolol or topiramate AND 2) Botox.

# ALDURAZYME

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## Products Affected

- Aldurazyme

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	Dosing consistent with product label: 0.58 mg/kg IV once weekly.



# ALINIA

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## Products Affected

- Alinia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D and cryptosporidiosis in HIV infected patients.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Cryptosporidiosis and Giardiasis: 3 days. Cryptosporidiosis, HIV: 14 days.
<b>Other Criteria</b>	N/A

# AMITIZA

## Products Affected

- Amitiza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Chronic Idiopathic Constipation, initial: documentation of fewer than 3 spontaneous bowel movements per week and a 6 month history of one or more of the following symptoms at least 25% of the time including straining, hard stools, or sensation of incomplete evacuation. 2) Irritable Bowel Syndrome, initial: female gender. 3) Opioid-induced constipation in adults with chronic non-cancer pain, initial: documentation of fewer than 3 spontaneous bowel movements per week and at least 25% of the bowel movements are associated with hard to very hard stools, moderate to very severe straining or sensation of incomplete evacuation. Renewal: Documentation of a significant reduction in constipation measured objectively and abdominal pain.
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: Lifetime.
<b>Other Criteria</b>	Chronic Idiopathic Constipation and Opioid-Induced Constipation, initial: failure of lactulose and polyethylene glycol 3350.

# AMPYRA

## Products Affected

- Ampyra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	History of seizure or moderate or severe renal impairment defined as creatinine clearance less than or equal to 50 mL/min.
<b>Required Medical Information</b>	Initial criteria: medical record documentation of 1) Diagnosis of multiple sclerosis, 2) Prior to initiation of therapy, the patient must have a timed 25-foot walk time to establish a baseline to evaluate treatment response, and 3) Documented Expanded Disability Status Score (EDSS) between 4.5 and 6.5. Three month renewal criteria: 1) Medical record documentation of an improvement in the timed 25-foot walk time compared to baseline maximum walk speed and 2) EDSS score remains 6.5 or below or documentation that the patient does not require constant bilateral support with a cane, crutch or brace to walk 20 meters without resting. Continuation thereafter: 1) Maintenance of the initial improvement and 2) EDSS score remains 6.5 or below.
<b>Age Restrictions</b>	Age at least 18 years.
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	If indicated, must be receiving concurrent therapy with a disease modifying agent such as Avonex, Betaseron, Extavia, Copaxone, Glatopa, Rebif, Gilenya, Aubagio, Tecfidera, Tysabri, Novantrone.

# ANADROL-50

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## Products Affected

- Anadrol-50

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Carcinoma of the prostate or breast in males. 2) Carcinoma of the breast in females with hypercalcemia. 3) Known or suspected pregnancy. 4) Nephrosis or the nephrotic phase of nephritis. 5) Severe hepatic dysfunction.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hematologist and Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# APOKYN

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## Products Affected

- Apokyn INJ 30MG/3ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal: Documentation that the patient's off time has been reduced with Apokyn.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	Initial: 3 month. Renewal: Lifetime.
<b>Other Criteria</b>	Initial: Documentation of failure of maximum tolerable doses of oral levodopa/carbidopa and one of the following: selegiline, ropinirole, pramipexole, tolcapone and entacapone.

# APTIOM

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## Products Affected

- Aptiom

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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, and levetiracetam.

# ARALAST

## Products Affected

- Aralast Np INJ 1000MG, 500MG, 800MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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 between 30% to 65% 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# ARCALYST

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## Products Affected

- Arcalyst

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal criteria: Medical record documentation of significant improvements in symptoms including joint pain, rash, feelings of fever or chills, eye redness, eye pain, or fatigue.
<b>Age Restrictions</b>	Age at least 12 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 month. Renewal: 12 months.
<b>Other Criteria</b>	N/A



# ARISTADA

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## Products Affected

- Aristada

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Evidence that the patient is currently taking oral aripiprazole from claims history or medical record documentation.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	N/A

# ARIXTRA

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## Products Affected

- Fondaparinux Sodium

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Major Bleeding, severe renal impairment (CrCl less than 30mL/min), bacterial endocarditis, thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium, body weight less than 50 kg (venous thromboembolism prophylaxis only).
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	<i>Pending review</i>
<b>Other Criteria</b>	N/A

# ARMODAFINIL

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## Products Affected

- Armodafinil

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal: documentation of significant improvement in daytime sleepiness and functioning.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: lifetime.
<b>Other Criteria</b>	For excessive sleepiness associated with narcolepsy, initial: Documented failure of a formulary stimulant such as methylphenidate or dextroamphetamine

# ASTAGRAF

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## Products Affected

- Astagraf XL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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.

# AUBAGIO

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## Products Affected

- Aubagio

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Documentation that Aubagio is being requested for monotherapy and is not intended to be used in combination with other multiple sclerosis agents.

# AUSTEDO

## Products Affected

- Austedo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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: requires 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: 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>	For Huntington's disease: prescriber restricted to a neurologist or in consultation with. For tardive dyskinesia: prescribing restricted to a neurologist, movement disorder specialist or a psychiatrist or in consultation with.
<b>Coverage Duration</b>	HD Initial: 3 months. TD Initial: 6 months. Renewal for HD and TD: 12 months.
<b>Other Criteria</b>	For Huntington's disease: failure of or contraindication to tetrabenazine which requires prior authorization. For tardive dyskinesia: failure of or contraindication to Ingrezza which requires prior authorization.

# BANZEL SUSPENSION

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## Products Affected

- Banzel SUSP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Documentation of an inability to take solid oral dosage forms.

# BENLYSTA

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## Products Affected

- Benlysta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Active lupus nephritis, severe active CNS lupus or used in combination with other biologics or 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>	Rheumatologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A



# BENZNIDAZOLE

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## Products Affected

- Benznidazole

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Chagas disease caused by <i>T. cruzi</i> confirmed by detection of <i>T. cruzi</i> trypomastigotes on microscopy, detection of <i>T. cruzi</i> DNA by PCR assay, or 2 positive diagnostic serologic tests using two different techniques and antigens showing IgG antibodies to <i>T. cruzi</i> .
<b>Age Restrictions</b>	Age at least 2 to 12 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist or cardiologist
<b>Coverage Duration</b>	60 days
<b>Other Criteria</b>	N/A

# BEXSERO

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## Products Affected

- Bexsero

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Age 10-25 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Series of 2 doses
<b>Other Criteria</b>	N/A

# BOSENTAN

## Products Affected

- Tracleer

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Concomitant administration with cyclosporine A or glyburide. 2) Pregnancy.
<b>Required Medical Information</b>	Initial: 1) Cardiac catheterization: mean Pulmonary Artery Pressure (mPAP) of at least 25 mmHg at rest, pulmonary capillary wedge pressure (PCWP) of less than 16 mmHg at rest, and New York Heart Association (NYHA) Class II-IV, 2) if female and of childbearing age, use of two reliable methods of birth control, 3) Baseline liver aminotransferases less than three times the upper limit of normal (ULN), and 5) Documented objective, measurable treatment goals to assess response to a 12-16 week trial such as an increase in the 6-minute walk test, decrease in dyspnea fatigue rating and other symptoms, evidence of improvement in hemodynamic mPAP or PVR, improvement in NYHA class, or lack of functional or hemodynamic deterioration. Renewal: Monthly monitoring of LFTs and medical record documentation indicating objective treatment goals are met.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	Initial: 16 weeks. Renewal: 12 months.
<b>Other Criteria</b>	<i>Pending review</i>

# BOTULINUM TOXIN

## Products Affected

- Botox
- Xeomin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Migraine renewal criteria (For Botox only): 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: documentaiton of treatment response including a decrease in the number of incontinence episodes or frequency. 3) 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months, 4 dose series.
<b>Other Criteria</b>	1) Migraine prophylaxis (For Botox only): failure of propranolol and topiramate. 2) Urinary incontinence (For Botox only): failure of oxybutynin and tolterodine.

# BRIVIACT

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## Products Affected

- Briviact

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	<i>Pending review</i>

# BUPHENYL

## Products Affected

- Sodium Phenylbutyrate POWD  
3GM/TSP

- Sodium Phenylbutyrate TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Use as emergency treatment of acute hyperammonemia.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	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/m <sup>2</sup> /day in larger patients. Maximum dose is 20 G/day.

# BUPRENORPHINE PATCH

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## Products Affected

- Buprenorphine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Failure of morphine sulfate ER or a prescriber supporting statement why morphine sulfate ER cannot be used.

# CANCER DRUGS

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## Products Affected

- Abraxane
- Adriamycin INJ 2MG/ML
- Adrucil INJ 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Afinitor
- Afinitor Disperz
- Alecensa
- Alimta
- Aliqopa
- Alunbrig
- Arranon
- Avastin
- Bavencio
- Beleodaq
- Bexarotene
- Bicnu
- Bortezomib
- Bosulif
- Braftovi
- Busulfan
- Cabometyx
- Calquence
- Caprelsa
- Clofarabine
- Cometriq
- Cotellic
- Cyramza
- Dacarbazine INJ 200MG
- Dactinomycin
- Darzalex
- Daunorubicin Hcl INJ 20MG/4ML
- Daunorubicin Hydrochloride INJ 20MG/4ML
- Docetaxel INJ 140MG/7ML, 160MG/16ML, 200MG/10ML, 200MG/20ML, 20MG/2ML, 20MG/ML, 80MG/4ML, 80MG/8ML
- Doxorubicin Hcl INJ 10MG, 2MG/ML, 50MG
- Doxorubicin Hcl Liposome
- Empliciti
- Erbitux INJ 100MG/50ML
- Erivedge
- Erleada
- Erwinaze
- Fareston
- Farydak
- Faslodex INJ 250MG/5ML
- Firmagon
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Folutyn
- Gilotrif
- Halaven
- Herceptin
- Ibrance
- Iclusig
- Idarubicin Hcl
- Idarubicin Hydrochloride INJ 20MG/20ML, 5MG/5ML
- Idhifa
- Imatinib Mesylate
- Imbruvica CAPS
- Imbruvica TABS 280MG, 420MG, 560MG
- Imfinzi
- Inlyta
- Iressa
- Istodax
- Istodax (overfill)
- Jakafi
- Jevtana
- Kadcyła
- Keytruda
- Kisqali
- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose
- Kyprolis INJ 30MG, 60MG
- Lartruvo



- 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
- Lonsurf
- Lynparza
- Mekinist
- Mektovi
- Melphalan Hydrochloride
- Mitomycin INJ 20MG, 40MG, 5MG
- Mustargen
- Mutamycin
- Mylotarg
- Nexavar
- Ninlaro
- Nipent
- Odomzo
- Opdivo
- Oxaliplatin INJ 100MG, 100MG/20ML
- Perjeta
- Pomalyst
- Proleukin
- Revlimid
- Romidepsin
- Rubraca
- Rydapt
- Sprycel
- Stivarga
- Sutent
- Sylatron
- Synribo
- Tafinlar
- Tagrisso
- Tarceva
- Targretin GEL
- Tassigna
- Tecentriq
- Temsirolimus
- Thiotepa INJ 15MG
- Tibsovo
- Treanda
- Trelstar Mixject
- Tretinoin CAPS
- Tykerb
- Valchlor
- Vectibix INJ 100MG/5ML
- Velcade
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Votrient
- Vyxeos
- Xalkori
- Xtandi
- Yervoy
- Yondelis
- Yonsa
- Zaltrap
- Zanosar
- Zejula
- Zelboraf
- Zolinza
- Zydelig
- Zykadia
- Zytiga

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	<i>Pending review</i>
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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.

# CARBAGLU

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## Products Affected

- Carbaglu

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 1) Diagnosis confirmed by DNA testing and 2) Objective, measurable treatment goals are provided. Renewal: Medical record documentation of stabilization of disease progression such as stabilization of neurologic impairments or seizures.
<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

# CAYSTON

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## Products Affected

- Cayston

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medical record documentation of 1) FEV1 between 25% and 75% predicted and 2) Pseudomonas aeruginos infection.
<b>Age Restrictions</b>	Age at least 7 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Documentation of failure of or resistance to tobramycin (TOBI).

# CERDELGA

## Products Affected

- Cerdelga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Initial: Medical record documentation of 1) Diagnostic confirmation by one of the following: a) biochemical assay of glucocerebrosidase activity in white blood cells 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) Documentation from a FDA-cleared test that the patient is an extensive, intermediate or poor CYP2D6 metabolizer and 4) Objective, measurable treatment goals.</p> <p>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).</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medical record documentation that the patient is not a candidate for laparoscopic cholecystectomy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Trial and failure of ursodiol.

# CHOLBAM

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## Products Affected

- Cholbam

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Renewal criteria after 3 months of initiating treatment: medical record documentation of liver function improvement and lack of complete biliary obstruction. 2) Ongoing renewal criteria: lack of complete biliary obstruction.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 4 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A



# CHORIONIC GONADOTROPIN

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## Products Affected

- Chorionic Gonadotropin INJ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Precocious puberty. 2) Pregnancy. 3) Prostate cancer or other androgen-dependent neoplasm. 4) Not covered to promote fertility.
<b>Required Medical Information</b>	For hypogonatropic hypogonadism: total testosterone level less than 300 ng/dL or free testosterone level below the normal range for age and gender.
<b>Age Restrictions</b>	Age at least 4 years.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Cryptorchidism: 6 weeks. Hypogonadism: 12 months.
<b>Other Criteria</b>	For hypogonatropic hypogonadism: failure of testosterone cypionate or enanthate.

# CIMZIA

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## Products Affected

- Cimzia

- Cimzia Starter Kit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<i>Pending review</i>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Rheumatologist, dermatologist or gastroenterologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	<i>Pending review</i>

# CINRYZE

## Products Affected

- Cinryze

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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. For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history.2) History of at least two attacks per month with airway swelling, severe abdominal pain, facial swelling and painful facial distortion that significantly interrupts usual daily activity despite short-term symptomatic treatment. 3) An evaluation of triggers (such as stress, hormonal changes, dental surgery, trauma, and medications include ACE inhibitors and estrogen) has been done and avoidance of triggers is being maximally managed. Renewal criteria for long term prevention: Documentation of at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity and duration of attacks or clinical documentation of functional improvement.
<b>Age Restrictions</b>	<i>Pending review</i>
<b>Prescriber Restrictions</b>	Hematologist, allergist or immunologist
<b>Coverage Duration</b>	Short term prevention: 1 procedure. Long term prevention initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# CITALOPRAM 40MG

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## Products Affected

- Citalopram Hydrobromide TABS 40MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Not covered for members age 60 years and older who newly start on citalopram and using more than 20mg of citalopram per day.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Prior Authorization applies to members who newly start on citalopram and are 60 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	N/A

# CLONAZEPAM ODT

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## Products Affected

- Clonazepam Odt

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members regardless of age who newly start on the drug: documentation of an inability to take solid oral dosage forms.

## COLONY STIMULATING FACTORS

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### Products Affected

- Fulphila
- Granix
- Leukine INJ 250MCG
- Neulasta
- Neupogen
- Zarxio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D and AIDS Neutropenia (Leukine and Neupogen) and Myelodysplastic Syndromes (Leukine and Neupogen).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of one the following: a) receiving myelosuppressive chemotherapy for a non-myeloid malignancy, receiving chemotherapy for AML, or post-induction chemotherapy for AML (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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	<i>Pending review</i>

# CORLANOR

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## Products Affected

- Corlanor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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.

# COSENTYX

## Products Affected

- Cosentyx

- Cosentyx Sensoready Pen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Plaque psoriasis 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Dermatologist or Rheumatologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	1) For the treatment of plaque psoriasis: failure of Humira or Enbrel with prior authorization. 2) For the treatment of psoriatic arthritis and ankylosing spondylitis: failure of Humira and Enbrel with prior authorization.



# CRESEMBA

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## Products Affected

- Cresemba

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	For the treatment of invasive aspergillosis (not required for invasive mucormycosis): failure of voriconazole.

# CYSTADANE

## Products Affected

- Cystadane

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
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	Dosing consistent with product label: Children age 3 and older and adults- 3g po twice daily. Dose may be gradually increased until plasma homocysteine exists in small amounts or is undetectable. Less than 3 years: 100mg/kg/day. Increase dose weekly by 100mg/kg until plasma homocysteine exists in small amounts or is undetectable.

# CYSTARAN

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## Products Affected

- Cystaran

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: 1) Medical record documentation of corneal cysteine crystal deposits. Renewal criteria: medical record documentation of a reduction in the Corneal Cysteine Crystal Score or improvement in the accumulation of corneal deposits.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Doctor who specialize in genetic or metabolic disorders or ophthalmologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# DALIRESP

## Products Affected

- Daliresp

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Diagnosis of severe COPD supported by 1) pulmonary function tests, FEV1 below 50% of predicted and 2) At least one documented moderate (require systemic steroid use such as prednisone or methylprednisolone) or severe (resulting in hospitalization) exacerbation in the last 12 month. Renewal: Documentation of clinical benefit such as reduction in hospitalizations, improvement in lung function or disease stabilization.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	Documentation of exacerbations while on a long-acting beta agonist (Serevent) and a long-acting anticholinergic (Spiriva) medication. May include combination inhalers that contain these drugs.

# DEMSEER

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## Products Affected

- Demser

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of scheduled surgical resection or if no surgical intervention planned, documentation of contraindication to surgery or malignant pheochromocytoma.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist, Oncologist or Nephrologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# DESVENLAFAXINE

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## Products Affected

- Desvenlafaxine Er

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant use of MAO inhibitors within the proceeding 14 days prior to desvenlafaxine.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Documentation of lack of efficacy or significant adverse effects with 1) one selective serotonin reuptake inhibitor such as sertraline, paroxetine (requires prior authorization for members who newly start on paroxetine and are age 65 and older), fluoxetine, citalopram or escitalopram and 2) venlafaxine or venlafaxine XR.

# DICLOFENAC 3% GEL

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## Products Affected

- Diclofenac Sodium GEL 3%

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	90 days
<b>Other Criteria</b>	Medical record documentation of failure of or contraindication to imiquimod and topical 5-fluorouracil.

# DOPTELET

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## Products Affected

- Doptelet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Platelets less than 50k.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterology, Hepatology, Hematology
<b>Coverage Duration</b>	5 days
<b>Other Criteria</b>	Documentation of upcoming procedure.



# DRONABINOL

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## Products Affected

- Dronabinol

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D and 1) cancer-related anorexia 2) nausea and vomiting associated with HIV/AIDS.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	The following criteria only applies to the treatment of nausea and vomiting associated with cancer chemotherapy or HIV: 1) failure of at least one of the following antiemetics: dimenhydrinate, meclizine, metoclopramide, promethazine, or prochlorperazine and 2) ondansetron.

# DUPIXENT

## Products Affected

- Dupixent

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: body surface area involvement $\geq$ 10% at baseline and functional impairment due to atopic dermatitis such as limitations in ADLs, sleep disturbances or skin infections. 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.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribing restricted to a dermatologist, allergist or immunologist or in consultation with.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Failure of or contraindication to 1) one of the following very high potency topical steroids: augmented betamethasone, clobetasol or halobetasol and 2) tacrolimus ointment which requires prior authorization.

# DUREZOL

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## Products Affected

- Durezol

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Failure of two of the following ophthalmic corticosteroids: fluorometholone, prednisolone or dexamethasone.

# EGRIFTA

## Products Affected

- Egrifta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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) History of diabetes requiring medication, 5) Body mass index less than or equal to 20 kg/m <sup>2</sup> . 5) Not approved for use in patients without HIV infection.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist or HIV specialist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# ELAPRASE

## Products Affected

- Elaprase

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Dosing consistent with product label: 0.5mg/kg IV once weekly.

# ELMIRON

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## Products Affected

- Elmiron

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal criteria for the treatment of interstitial cystitis: medical record documentation of an improvement in symptoms such as a reduction in bladder pain.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	N/A

# EMEND

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## Products Affected

- Aprepitant

- Emend SUSR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant use of pimozide.
<b>Required Medical Information</b>	Confirmation of diagnosis and use as prophylaxis and not for established nausea and vomiting.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	PONV: one dose. Chemotherapy: 12 months.
<b>Other Criteria</b>	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.

# EMFLAZA

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## Products Affected

- Emflaza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal criteria: documentation of a positive treatment response (e.g. pulmonary function, muscle strength, functional ability, walk tests)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation of a neurologist or a specialist in Duchenne Muscular Dystrophy or neuromuscular disorders
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Failure of or adverse effects to prednisone.



# EMSAM

## Products Affected

- Emsam

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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 (requires prior authorization for members who newly start on paroxetine and are age 65 and older) or sertraline, 2) venlafaxine, 3) bupropion or 4) mirtazapine.

# ENBREL

## Products Affected

- Enbrel

- Enbrel Sureclick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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) Ankylosing spondylitis (AS) Renewal: Improved functioning and/or symptoms. 4) Plaque psoriasis (PP) a) PP initial: involvement of more than 5% of body surface area or hand, foot, face, or genital involvement. b) PP renewal: improvement in affected BSA, plaque severity and/or functioning. 5) Juvenile idiopathic arthritis (JIA) renewal: Improved functioning and/or improvement in tender joint count and swollen joint count.
<b>Age Restrictions</b>	JIA: age at least 2 years
<b>Prescriber Restrictions</b>	Rheumatologist or Dermatologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	1) RA Initial: failure of methotrexate and at least one other DMARD such as leflunomide, cyclosporine, sulfasalazine, azathioprine or hydroxychloroquine. 2) PsA initial: failure of one oral NSAID and methotrexate. 3) AS initial: failure of one oral NSAID. 4) PP initial: failure of methotrexate or cyclosporine. 5) JIA initial: failure of methotrexate for at least 8 weeks. 6) For all diagnoses: not on concurrent therapy with other immune modulators such as adalimumab, anakinra, abatacept, and infliximab.

# ENDARI

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## Products Affected

- Endari

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal criteria: medical record documentation that the drug has been effective in reducing the number of sickle cell crisis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	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.

# ENTRESTO

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## Products Affected

- Entresto

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medical record documentation of all of the following: 1) Ejection fraction less than or equal to 40%, 2) New York Heart Association (NYHA) Functional Class II to IV and 3) Currently on appropriate therapy including beta blockers and angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cardiologist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	N/A

# EPCLUSA

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## Products Affected

- Epclusa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 1) 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

# ERYTHROPOIESIS-STIMULATING AGENTS

## 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, 300MCG/ML,  
40MCG/0.4ML, 40MCG/ML,  
500MCG/ML, 60MCG/0.3ML,  
60MCG/ML
- Procrit
- Retacrit

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D and zidovudine-induced anemia in HIV/AIDS patients.
<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.
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## EXJADE/FERRIPROX

### Products Affected

- Exjade

- Ferriprox

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For chronic iron overload due to blood transfusions (Exjade and Ferriprox) Initial: Serum ferritin 1000-8000ng/ml. For non-transfusion-dependent thalassemia syndromes (Exjade 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. Renewal criteria for all indications: 1) Documentation of compliance with recommended monitoring of monthly ferritin, serum creatinine, urine protein, LFTs, and yearly auditory and ophthalmic testing and 2) reduction in total body iron, evidenced by decreased ferritin levels.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For chronic iron overload due to blood transfusions, Initial: Failure of deferoxamine or reason why deferoxamine cannot be used.



# EXONDYS

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## Products Affected

- Exondys 51

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Neurologist or in consultation with a neurologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# FABRAZYME

## Products Affected

- Fabrazyme

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Age at least 8 years.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Dosing consistent with product label: 1 mg/kg IV infusion every 2 weeks.

# FARXIGA

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## Products Affected

- Farxiga
- Qtern
- Xigduo Xr

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: HbA1c above 7%.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	1) Monotherapy Initial: Failure of maximum tolerated doses of 2 of the following: metformin, sulfonylurea and thiazolidinedione. 2) Combination Therapy Initial: Failure of to maximum tolerated doses of combination therapy with 2 of the following: metformin, sulfonylurea and thiazolidinedione.

# FASENRA

## Products Affected

- Fasenra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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. Renewal criteria: documentation of or claims history showing a reduction in the use of oral steroids or reduction in asthma symptoms.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist, Allergist, or Immunologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Failure of an inhaled corticosteroid and a long-acting beta agonist.

# FETZIMA

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## Products Affected

- Fetzima

- Fetzima Titration Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Failure of or intolerance to venlafaxine and duloxetine.

# FIRAZYR

## Products Affected

- Firazyr

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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. For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history. 2) History of at least two attacks per month with airway swelling, severe abdominal pain, facial swelling and painful facial distortion that significantly interrupts usual daily activity despite short-term symptomatic treatment. 3) An evaluation of triggers (such as stress, hormonal changes, dental surgery, trauma, and medications include ACE inhibitors and estrogen) has been done and avoidance of triggers is being maximally managed. Renewal criteria for long-term prevention: Documentation of a reduction in symptoms such as abdominal pain, cutaneous pain and cutaneous swelling.
<b>Age Restrictions</b>	Age at least 18 years.
<b>Prescriber Restrictions</b>	Hematologist, allergist or immunologist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	Trial and failure of or contraindication to danazol.

# FORTEO

## Products Affected

- Forteo INJ 600MCG/2.4ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	1) Postmenopausal female with either a) evidence of recent radiographic osteoporotic fracture while compliant on a bisphosphonate or b) 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to a maximum of 24 months. Use is not recommended for longer.
<b>Other Criteria</b>	Failure of or contraindication to an oral bisphosphonate.

# FYCOMPA

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## Products Affected

- Fycompa TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: 1) For the treatment of partial-onset seizures: failure of two of the following: carbamazepine, oxcarbazepine, 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, lamotrigine, phenytoin, carbamazepine and levetiracetam.



# FYCOMPA SUSPENSION

## Products Affected

- Fycompa SUSP

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
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: a) failure of two of the following: carbamazepine, oxcarbazepine, phenytoin, topiramate, divalproex, felbamate, tiagabine, lamotrigine, gabapentin, zonisamide, and levetiracetam. b) reason why liquid formulation is needed over oral tablets of Fycompa. 2) For the treatment of primary generalized tonic-clonic seizures: a) failure of two of the following topiramate, lamotrigine, phenytoin, carbamazepine and levetiracetam. b) reason why liquid formulation is needed over oral tablets of Fycompa.</p>

# GARDASIL

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## Products Affected

- Gardasil 9

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Age 9-26 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Series of 3 doses
<b>Other Criteria</b>	N/A

# GATTEX

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## Products Affected

- Gattex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Age at least 18 years.
<b>Prescriber Restrictions</b>	Gastroenterologist or GI specialist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# GILENYA

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## Products Affected

- Gilenya

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Documentation that Gilenya is being requested for monotherapy and is not intended to be used in combination with other multiple sclerosis agents.

# GRANISETRON

## Products Affected

- Granisetron Hcl INJ 0.1MG/ML, 1MG/ML
- Granisetron Hcl TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Nausea and vomiting, cancer treatment: 12 months. Post-operative nausea and vomiting: one dose.
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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. For hereditary angioedema Type III, documentation of diagnosis confirmed by genetic testing, normal complement studies combined with clinical features of angioedema or family history.2) History of at least two attacks per month with airway swelling, severe abdominal pain, facial swelling or painful facial distortion that significantly interrupts usual daily activity despite short-term symptomatic treatment. 3) An evaluation of triggers (such as stress, hormonal changes, dental surgery, trauma, and medications include ACE inhibitors and estrogen) has been done and avoidance of triggers is being maximally managed. 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribing restricted to or in consultation with a hematologist, allergist or an immunologist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	Failure of or a reason why danazol cannot be used.

# HARVONI

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## Products Affected

- Harvoni

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 1) 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance
<b>Other Criteria</b>	Harvoni with or without ribavirin will be approved as requested consistent with FDA approved labeling or AASLD/IDSA guidelines.

# HETLIOZ

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## Products Affected

- HetlioZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: medical record documentation of complete blindness or those with retinas that are entirely nonfunctioning. Renewal criteria: documentation of an increase in nighttime sleeping and decrease in daytime napping.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A



## HIGH RISK MEDICATION - ANTIDEPRESSANTS

### Products Affected

- Amitriptyline Hcl TABS
- Amoxapine
- Clordiazepoxide/amitriptyline
- Clomipramine Hcl CAPS
- Desipramine Hcl TABS
- Doxepin Hcl CAPS
- Doxepin Hcl CONC
- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Nortriptyline Hcl CAPS
- Nortriptyline Hcl SOLN
- Perphenazine/amitriptyline
- Protriptyline Hcl
- Trimipramine Maleate CAPS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The following criteria applies to members who newly start on the drug and are 65 and older: 1) Documentation that the drug is being used for a medically accepted indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: 1) For the treatment of depression, failure of two of the following agents: citalopram, escitalopram, fluoxetine, sertraline, venlafaxine, duloxetine, bupropion, or mirtazapine. 2) For migraine prevention, failure of two of the following agents: topiramate, valproic acid/divalproex acid, or a formulary beta blocker such as propranolol. 3) For the treatment of obsessive compulsive disorder (clomipramine): failure of two of the following agents: citalopram, escitalopram, fluoxetine, sertraline, venlafaxine, mirtazapine, fluvoxamine.

## HIGH RISK MEDICATION - ANTIHYPERTENSIVES

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**Products Affected**

- Guanfacine Hcl
- Methyldopa TABS 250MG, 500MG
  - Methyldopa/hydrochlorothiazide

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks. 3) Renewal after 3 months: Documentation of a reduction in blood pressure from baseline. 4) Renewal after 12 months: the prescriber must reaffirm that the benefits outweigh the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months
<b>Other Criteria</b>	Failure of one combination therapy with 2 of the following: thiazide diuretic, ACE inhibitor, angiotensin II receptor antagonist, and calcium channel blocker.

# HIGH RISK MEDICATION - ANTIPARKINSON AGENTS

## Products Affected

- Benztropine Mesylate TABS

- Trihexyphenidyl Hcl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	For Parkinson's Disease, failure of two of the following: levodopa/carbidopa, pramipexole, ropinirole, bromocriptine, selegiline, rasagiline, entacapone. For extrapyramidal symptoms induced by antipsychotics: a) evidence from claims history that the patient is on an antipsychotic or medical record documentation that EPS is due to an antipsychotic and b) failure of amantadine or reason why amantadine cannot be used.

## HIGH RISK MEDICATION - ANTIPLATELET DRUGS

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### Products Affected

- Dipyridamole TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	For stroke prevention: documentation of failure of aspirin-dipyridamole and clopidogrel.

# HIGH RISK MEDICATION - BUTALBITAL

## Products Affected

- Ascomp/codeine
- Butalbital Compound TABS
- Butalbital/acetaminophen TABS 325MG; 50MG
- Butalbital/acetaminophen/caffeine CAPS
- Butalbital/acetaminophen/caffeine TABS 325MG; 50MG; 40MG
- Butalbital/acetaminophen/caffeine/codeine
- Butalbital/aspirin/caffeine/codeine
- Marten-tab
- Tencon TABS 325MG; 50MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Initial: documentation that the drug is being used for a FDA-approved indication and the prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks. 3) Renewal after 3 months: Documentation of a reduction in the frequency or intensity of headaches from baseline. 3) Renewal after 12 months: the prescriber must reaffirm that the benefits outweigh the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	For tension type headache: documentation of failure of two nonsteroidal anti-inflammatory drugs such as ibuprofen, naproxen, aspirin, ketoprofen, diclofenac or reason why NSAIDs cannot be used.

## HIGH RISK MEDICATION - CLEMASTINE

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### Products Affected

- Clemastine Fumarate TABS 2.68MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<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 levocetirizine and desloratadine.

# HIGH RISK MEDICATION - DIGOXIN

**Products Affected**

- Digitek TABS 0.25MG
- Digox TABS 250MCG
- Digoxin TABS 250MCG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	1) For members age 65 and older: a) Documentation that the drug is being used for a FDA-approved indication and b) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks. 2) Documentation that lower doses of digoxin have been ineffective to treat the patient’s condition or reducing the dose would cause adverse effects for the patient.
Age Restrictions	Prior Authorization applies to patients 65 years or older.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

# HIGH RISK MEDICATION - DISOPYRAMIDE

## Products Affected

- Disopyramide Phosphate CAPS
- Norpace Cr

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	For the treatment of ventricular arrhythmia: failure of two formulary alternatives not considered to be high risk medications or reason why these alternatives would be inappropriate to use. Formulary alternatives include quinidine gluconate, amiodarone or flecainide.



## HIGH RISK MEDICATION - ERGOLOID MESYLATES

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### Products Affected

- Ergoloid Mesylates TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	For Alzheimer's Disease, failure of two of the following: donepezil, galantamine, rivastigmine and memantine.

# HIGH RISK MEDICATION - ESTROGENS AND PROGESTINS

## Products Affected

- Amabelz
- Estradiol ORAL TABS 0.5MG, 1MG, 2MG
- Estradiol PTTW
- Estradiol PTWK
- Estradiol/norethindrone Acetate
- Estropipate TABS 0.75MG
- Lopreeza
- Menest TABS 0.3MG, 0.625MG, 1.25MG
- Mimvey
- Mimvey Lo
- Prefest

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older (Initial and Renewal): 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Criteria does not apply to the following diagnoses: palliative treatment of metastatic breast cancer, palliative treatment of advanced androgen-dependent prostate cancer. For prophylaxis of postmenopausal osteoporosis: failure of two non-estrogen therapies such as alendronate, ibandronate, Actonel or Evista. For moderate to severe vulvar and vaginal atrophy associated with menopause: failure of two vaginal estrogens including estrogen cream (Premarin or Estrace Cream), E-string, or Vagifem.

## HIGH RISK MEDICATION - HYDROXYZINE

### Products Affected

- Hydroxyzine Hcl INJ
- Hydroxyzine Hcl SYRP
- Hydroxyzine Hcl TABS 10MG, 25MG
- Hydroxyzine Hydrochloride TABS 50MG
- Hydroxyzine Pamoate CAPS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a medically accepted indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	1) For the treatment of pruritus: failure of two topical steroids such as betamethasone, hydrocortisone, triamcinolone, fluocinonide, fluocinolone, aclometasone, amcinonide, desonide, mometasone, prednicarbate or fluticasone. 2) For the treatment of anxiety: failure of two of the following a) buspirone, b) a selective serotonin reuptake inhibitor such as escitalopram or paroxetine (requires prior authorization for members who newly start on paroxetine and are age 65 and older) or c) a serotonin-norepinephrine reuptake inhibitor such as venlafaxine or duloxetine. 3) For the treatment of allergic rhinitis: documentation of failure of levocetirizine and desloratadine.

## HIGH RISK MEDICATION - MEGESTROL

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### Products Affected

- Megestrol Acetate SUSP 40MG/ML
- Megestrol Acetate TABS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Not covered for anorexia or to gain weight alone.
Required Medical Information	N/A
Age Restrictions	Prior Authorization applies to patients 65 years or older.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	The following criteria only applies for the treatment of cachexia associated with HIV/AIDs, failure of dronabinol (requires prior authorization) or reason why it would be inappropriate to use.

# HIGH RISK MEDICATION - NITROFURANTOIN

## Products Affected

- Nitrofurantoin Macrocrystals
- Nitrofurantoin Monohydrate
- Nitrofurantoin Monohydrate/macrocrystals

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Creatinine clearance must be at least 60 ml/min.
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	1) Authorization is required if the day supply is greater than 14 days. 2) Documentation of allergy to, drug interaction to or drug resistance to two of the following: trimethoprim/sulfamethoxazole DS, ciprofloxacin or trimethoprim.

# HIGH RISK MEDICATION - PAROXETINE

## Products Affected

- Paroxetine Hcl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The following criteria applies to members who newly start on the drug and are 65 and older: 1) Documentation that the drug is being used for a medically accepted indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: 1) For the treatment of depression, failure of two of the following agents: citalopram, escitalopram, fluoxetine, sertraline, venlafaxine, duloxetine, bupropion, or mirtazapine. 2) For the treatment of obsessive compulsive disorder: failure of two of the following agents: citalopram, escitalopram, fluoxetine, sertraline, venlafaxine, mirtazapine, fluvoxamine. 3) For the treatment of generalized anxiety disorder, failure of two of the following agents: escitalopram, duloxetine, or venlafaxine. 4) For all other medically accepted indications supported by drug references (compendia), failure of two non-high risk formulary alternatives if they also have the same accepted uses.

# HIGH RISK MEDICATION - PHENOBARBITAL

## Products Affected

- Phenobarbital ELIX 20MG/5ML
- Phenobarbital TABS 100MG, 15MG, 16.2MG, 30MG, 32.4MG, 60MG, 64.8MG, 97.2MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The following criteria applies to members who are 65 and older except for members who are currently on phenobarbital for seizures disorder: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	1) For the short term treatment of insomnia, failure of Silenor and Rozerem or reason why both would be inappropriate to use. 2) For the treatment of seizures, the following criteria applies to members who newly start on the drug: failure of or reason why two formulary alternatives cannot be used including carbamazepine, lamotrigine, topiramate, phenytoin, levetiracetam or valproic acid, 3) For sedation, failure of lorazepam or reason why lorazepam cannot be used.

## HIGH RISK MEDICATION - PROMETHAZINE

### Products Affected

- Phenadoz
- Promethazine Hcl INJ
- Promethazine Hcl SUPP
- Promethazine Hcl SYRP
- Promethazine Hcl TABS 12.5MG, 25MG
- Promethazine Hcl Plain
- Promethazine Hydrochloride TABS 50MG
- Promethazine Vc Plain
- Promethazine/phenylephrine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	1) For the treatment of nausea and vomiting: documentation of failure of two formulary alternatives including ondansetron, metoclopramide or prochlorperazine. 2) For the treatment of motion sickness: documentation of failure of meclizine. 3) For the treatment of allergic conditions: documentation of failure of levocetirizine and desloratadine. 4) For all other conditions: documentation that at least two formulary alternatives indicated to treat the patient's condition that are not considered a high risk medication have been failed or would be inappropriate to treat the patient's condition.



# HIGH RISK MEDICATION - SEDATIVE HYPNOTICS

## Products Affected

- Eszopiclone
- Temazepam
- Zaleplon
- Zolpidem Tartrate TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks. Acknowledgement is not required if the drug is being used for acute insomnia due to an upcoming procedure.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Procedural insomnia: 1 month. All other: 12 months.
<b>Other Criteria</b>	Documentation of failure of Rozerem (ramelton) and Silenor (doxepin 3mg, 6mg). Not required for acute insomnia due to an upcoming procedure.

# HIGH RISK MEDICATION - SKELETAL MUSCLE RELAXANTS

## Products Affected

- Chlorzoxazone TABS 500MG
- Cyclobenzaprine Hcl TABS 10MG, 5MG
- Methocarbamol TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	Prior Authorization applies to patients 65 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# HUMIRA

## Products Affected

- Humira
- Humira Pediatric Crohns Disease Starter Pack
- Humira Pen
- Humira Pen-cd/uc/hs Starter INJ 40MG/0.8ML
- Humira Pen-ps/uv Starter INJ 40MG/0.8ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>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 (PP) a) PP initial: duration of disease for at least 6 months covering more than 5% of body surface area or hand, foot, face, or genital involvement. b) PP 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 and/or elimination of signs of toxicity. 8) Hidradenitis suppurativa (HS) a) HS initial: moderate to severe disease evident by documentation of Hurley Stage II or III and at least 3 abscesses or inflammatory nodules. b) HS renewal: medical record documentation of a reduction in nodules or abscesses. 9) Uveitis a) Initial: documentation of non-infectious, intermediate, posterior or panuveitis b) 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.</p>
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA and PsA: Rheumatologist. PP/HS: Dermatologist. CD: Gastroenterologist. Uveitis: Ophthalmologist

<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	<p>1) Moderate to severe CD initial: failure of conventional therapy with at least one agent from the following drug classes a) aminosalicic acid derivatives (sulfasalazine or mesalamine) and b) immunosuppressants (azathioprine or methotrexate). 2) RA initial: a) failure of methotrexate and at least one other DMARD such as leflunomide, cyclosporine, sulfasalazine, azathioprine, or hydroxychloroquine. 3) PsA Initial: a) failure of conventional management with one oral NSAID and methotrexate. 4) AS initial: a) failure of one oral NSAID. 5) JIA Initial: failure of an 8 week trial of methotrexate. 6) PP Initial: failure of methotrexate or cyclosporine. 7) UC Initial: failure of two of the following a) oral aminosalicylates such as sulfasalazine, mesalamine, olsalazine, basalazide, b) oral prednisone, c) azathioprine or purinethol. 8) For all diagnoses: not on concurrent therapy with another immune modulator such as etanercept, abatacept, anakinra or infliximab.</p>

# ILARIS

## Products Affected

- Ilaris INJ 150MG/ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Cryopyrin associated periodic (CAP) syndrome including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome Renewal criteria: Medical record documentation of significant improvements in symptoms including joint pain, rash, feelings of fever or chills, eye redness, eye pain, or fatigue. 2) Systemic juvenile idiopathic arthritis (JIA) renewal: Improved functioning and/or improvement in tender joint count and swollen joint count. 3) For tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS), hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS)/mevalonate kinase deficiency (MKD) and familial Mediterranean fever (FMF) Renewal Criteria: Medical record documentation of significant improvements in symptoms including reduction in recurrent attacks and the risk of developing amyloidosis.
<b>Age Restrictions</b>	CAP: age at least 4 years. JIA: age at least 2 years.
<b>Prescriber Restrictions</b>	CAP: rheumatologist, dermatologist or immunologist. TRAPS, HIDS/MKD, FMF, JIA: rheumatologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Systemic juvenile idiopathic arthritis: failure of 1) methotrexate for at least 8 weeks and 2) Humira or Enbrel.

# INCRELEX

## Products Affected

- Increlex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Evidence of closure of epiphyseal plate. 2) Active or suspected neoplasia.
<b>Required Medical Information</b>	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. 2) Growth Hormone Gene Deletion Initial: evidence of gene deletion and (+) neutralizing antibodies to growth hormone.
<b>Age Restrictions</b>	Age 2-18 years
<b>Prescriber Restrictions</b>	Endocrinologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# INFLECTRA

## Products Affected

- Inflectra

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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) Ulcerative Colitis (UC) Renewal: decrease in frequency of bloody stools and/or elimination of signs of toxicity. 3) Rheumatoid Arthritis (RA) Renewal: Improvement in number of tender, swollen joints, improved function, ability to perform ADLs and/or pain. 4) Psoriatic Arthritis (PsA) Renewal: Improved functioning and/or decreased in number of tender, swollen joints and reduction in skin lesions and/or has disease stability. 5) Ankylosing Spondylitis (AS) Renewal: Improved functioning: 6) Plaque psoriasis (PP) a) PP initial: duration of disease for at least 6 months covering more than 10% of body surface area or hand, foot or mucous membrane involvement. PP Renewal: improvement in affected BSA, plaque severity and/or functioning.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist or rheumatologist or dermatologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.

<b>Other Criteria</b>	1) CD Initial: a) failure of or contraindication to an aminosalicyclic acid derivative and b) failure of or contraindication to methotrexate or azathioprine. 2) UC initial: a) failure of or contraindication to two of the following: aminosalicylates, prednisone, azathioprine or purinethol. 3) RA initial: a) failure of or contraindication to methotrexate and 2) failure of or contraindication to one other DMARD: leflunomide, cyclosporine, sulfasalazine, azathioprine or hydroxychloroquine and c) concurrent use with methotrexate unless contraindicated. 4) PsA Initial: a) failure of or contraindication to an oral NSAID and b) failure of or contraindication to methotrexate. 5) AS initial: a) failure of or contraindication to an oral NSAID. 6) PP initial: failure of or contraindication to methotrexate or cyclosporine. 7) For all diagnoses: not on concurrent therapy with another immune modulator such as abatacept, anakinra, etanercept, or adalimumab.
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# INGREZZA

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## Products Affected

- Ingrezza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal criteria: 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.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribing restricted to a neurologist, movement disorder specialist or a psychiatrist or in consultation with.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# INTERFERON ALFA-2B

## Products Affected

- Intron A

- Intron A W/diluent

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Decompensated cirrhosis or autoimmune hepatitis.
<b>Required Medical Information</b>	Chronic Hepatitis B (HBV): 1) Compensated cirrhosis and HBV DNA greater than 2000 IU/ml or 2) 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 3) 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. 4) No prior treatment with interferon.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist, Infectious Disease Specialist, GI specialist except for Condyloma acuminatum
<b>Coverage Duration</b>	Cancer: Lifetime. HBV: 12 months. HCV: Initial: 16 weeks and Renewal: 12 months. CA: 3 weeks.
<b>Other Criteria</b>	1) For Hepatitis C: Criteria will be applied consistent with current AASLD/IDSA guidance. Other therapies exists. 2) Condyloma Acuminatum (CA): Failure of conventional treatment with podofilox and imiquimod.

# INTRAVENOUS IMMUNE GLOBULIN

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## Products Affected

- Atgam
- Bivigam
- Carimune Nanofiltered INJ 12GM, 6GM
- Flebogamma Dif
- Gamastan
- Gamastan S/d
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked
- Gammaplex INJ 10GM/100ML; 0, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Octagam INJ 10GM/100ML, 1GM/20ML, 20GM/200ML, 2GM/20ML, 5GM/50ML
- Privigen
- Thymoglobulin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D and HIV, Allogeneic bone marrow transplant (BMT), pregnancy-associated idiopathic thrombocytopenic pupura, Myasthenia Gravis (MG), Autoimmune Mucocutaneous Blistering Disease (AMBD), Autoimmune Hemolytic Anemia, Warm Type (AHA-W), Polymyositis and Dermatomyositis.
<b>Exclusion Criteria</b>	N/A

<b>Required Medical Information</b>	<p>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 plasmaphoresis, 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.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	PI: Lifetime. All other diagnoses: 3 months.

<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.
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# INVEGA TRINZA

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## Products Affected

- Invega Trinza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The following criteria applies to members who newly start on the drug: Medical record documentation or evidence from claims history that Invega Sustenna has been used for 4 months.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Documented failure of or intolerance to Risperdal Consta.

# ISOTRETINOIN

## Products Affected

- Amnesteem
- Claravis
- Isotretinoin CAPS
- Myorisan
- Zenatane

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Females who are pregnant or who may become pregnant and are not using at least two forms of contraception.
<b>Required Medical Information</b>	Medical record documentation of 1) negative pregnancy test and use of reliable methods of birth control in females of child-bearing age and 2) Routine evaluation for significant depression, psychosis, or suicide potential, vision, hearing and liver enzymes.
<b>Age Restrictions</b>	Age at least 12 years.
<b>Prescriber Restrictions</b>	Dermatologist
<b>Coverage Duration</b>	20 weeks
<b>Other Criteria</b>	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.

# JADENU

## Products Affected

- Jadenu

- Jadenu Sprinkle

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For chronic iron overload due to blood transfusions, Initial: Serum ferritin 1000-8000ng/ml. For non-transfusion-dependent thalassemia syndromes, 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. Renewal criteria for all indications: 1) Documentation of compliance with recommended monitoring of monthly ferritin, serum creatinine, urine protein, LFTs, and yearly auditory and ophthalmic testing and 2) reduction in total body iron, evidenced by decreased ferritin levels.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For chronic iron overload due to blood transfusions, Initial: Failure of deferoxamine or reason why deferoxamine cannot be used.



# JARDIANCE

## Products Affected

- Glyxambi
- Jardiance
- Synjardy
- Synjardy Xr

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: HbA1c above 7% or evidence of cardiovascular disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria does not apply to patients who have diabetes and cardiovascular disease: 1) Monotherapy Initial: Failure of maximum tolerated doses of 2 of the following: metformin, sulfonylurea and thiazolidinedione or 2) Combination Therapy Initial: Failure of or contraindication to maximum tolerated doses of combination therapy with 2 of the following: metformin, sulfonylurea and thiazolidinedione.

# JUXTAPID

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## Products Affected

- Juxtapid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: diagnosis of homozygous familial hypercholesterolemia. Renewal criteria: reduction in LDL-C.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	<i>Pending review</i>

# JYNARQUE

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## Products Affected

- Jynarque

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Evidence of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD) as defined by either 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 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Nephrologist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	N/A

# KALYDECO

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## Products Affected

- Kalydeco

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# KEVEYIS

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## Products Affected

- Keveyis

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal criteria: medical record documentation of a reduction in the number, frequency or duration of paralytic attacks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# KINERET

## Products Affected

- Kineret

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA) Renewal: Improved functioning and/or improvement in tender joint count and swollen joint count.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For rheumatoid arthritis: Rheumatologist.
<b>Coverage Duration</b>	RA Initial: 6 mo. Renewal: 12 mo. Neonatal Onset Multi-system Inflammatory Disease: 12 mo.
<b>Other Criteria</b>	Rheumatoid Arthritis Initial: 1) failure of a) methotrexate for at least 8 weeks and b) at least one other Disease-modifying Antirheumatic Drug (DMARD) including leflunomide, cyclosporine, sulfasalazine, azathioprine or hydroxychloroquine. 2) Not on concurrent therapy with another immune modulator such as abatacept, infliximab, etanercept, or adalimumab.

# KORLYM

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## Products Affected

- Korlym

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	1) Documentation of failure of a) insulin therapy and b) one of the following: metformin, a sulfonylurea and a thiazolidinedione.

# KUVAN

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## Products Affected

- Kuvan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal: Documentation of response to therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: Lifetime.
<b>Other Criteria</b>	N/A



# KYNAMRO

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## Products Affected

- Kynamro

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: diagnosis of homozygous familial hypercholesterolemia. Renewal criteria: reduction in LDL-C.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	<i>Pending review</i>

# LETAIRIS

## Products Affected

- Letairis

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Initial: 1) Cardiac cath: Mean PAP greater than 24mm Hg at rest, and PCWP less than 16 mm Hg at rest, and WHO Class II-IV, 2) if female and of childbearing age, use of reliable methods of birth control, 3) Documented objective, measurable treatment goals to assess response to a 12-16 week trial such as an increase in the 6-minute walk test, or decrease in dyspnea fatigue rating and other symptoms, or evidence of improvement in hemodynamic mPAP or PVR or WHO class, or lack of functional or hemodynamic deterioration. Renewal: medical record documentation indicating objective treatment goals are met.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	Initial: 16 weeks. Renewal: 12 months.
<b>Other Criteria</b>	Failure of or contraindication to sildenafil and Tracleer (bosentan). Please note that both drugs require prior authorization.

# LEUPROLIDE

## Products Affected

- Eligard
- Leuprolide Acetate INJ
- Lupaneta Pack
- 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
Covered Uses	All FDA-approved indications not otherwise excluded from Part D and uterine leiomyoma (UL).
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (EM): requires laparoscopic confirmation of diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	EM: 6 mo. CPP: female age 11, male age 12. Anemia, UL: 3 mo. UL: 6 mo. Prostate cancer: Lifetime.
Other Criteria	N/A

# LEVOLEUCOVORIN

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## Products Affected

- Levoleucovorin

- Levoleucovorin Calcium INJ  
175MG/17.5ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist, rheumatologist, or gastroenterologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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.

# LIDOCAINE PATCHES

## Products Affected

- Lidocaine PTCH

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D, diabetic peripheral neuropathy and cancer neuropathic pain.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal: Medical record documentation of a reduction in specific, objective pain symptoms and/or improved functioning.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: Lifetime.
<b>Other Criteria</b>	1) For the treatment of post-herpetic neuralgia and diabetic peripheral neuropathy: medical record documentation of failure of gabapentin. 2) For the treatment of cancer neuropathic pain: failure of an antidepressant and gabapentin. Antidepressants include a tricyclic antidepressant (eg. amitriptyline, imipramine, nortriptyline, desipramine) duloxetine or venlafaxine. Prior Authorization applies to members who newly start a tricyclic antidepressant and are 65 years and older.

# LINZESS

## Products Affected

- Linzess CAPS 145MCG, 290MCG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Idiopathic Constipation, initial: documentation of fewer than 3 spontaneous bowel movements per week and a 6 month history of one or more of the following symptoms at least 25% of the time including straining, hard stools, or sensation of incomplete evacuation. Renewal criteria for chronic idiopathic constipation and irritable bowel syndrome with constipation: documentation of a reduction in constipation measured objectively and abdominal pain.
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: Lifetime.
<b>Other Criteria</b>	Chronic Idiopathic Constipation: failure of lactulose and polyethylene glycol 3350.

# LOTRONEX

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## Products Affected

- Alosetron Hydrochloride

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	<i>Pending review</i>
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 1 month. Renewal: Lifetime.
<b>Other Criteria</b>	<i>Pending review</i>

# LUCEMYRA

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## Products Affected

- Lucemyra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	N/A



# LUMIZYME

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## Products Affected

- Lumizyme

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Dosing consistent with product label: 20 mg/kg IV every 2 wk.

# MAVYRET

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## Products Affected

- Mavyret

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 1) 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance
<b>Other Criteria</b>	N/A

# MODAFINIL

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## Products Affected

- Modafinil

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal: documentation of significant improvement in daytime sleepiness and functioning.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: lifetime.
<b>Other Criteria</b>	The following criteria only applies for the treatment of excessive sleepiness associated with narcolepsy, Initial: Documented failure of a formulary stimulant such as methylphenidate, dexamethylphenidate, mixed amphetamine salts, or dextroamphetamine.

# MOZOBIL

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## Products Affected

- Mozobil

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist and hematologist
<b>Coverage Duration</b>	4 days
<b>Other Criteria</b>	Used in combination with a granulocyte colony stimulating factor.

# MULTAQ

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## Products Affected

- Multaq

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	NYHA Class IV heart failure. Symptomatic heart failure with recent decompensation requiring hospitalization.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cardiologist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Documentation of failure of or intolerance to amiodarone.

# MYALEPT

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## Products Affected

- Myalept

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Dosing consistent with the FDA approved labeling.

# NAGLAZYME

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## Products Affected

- Naglazyme

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Dosing consistent with product label: 1mg/kg IV once weekly.

# NASAL FENTANYL

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## Products Affected

- Lazanda

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Not approved for use of acute or postoperative pain and for opioid non-tolerant patients.
<b>Required Medical Information</b>	Documentation that Lazanda is being used for the treatment of breakthrough cancer pain.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist or Pain Specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Documentation of 1) Failure of one short-acting opioids (eg, oxycodone, morphine sulfate, etc) or if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting, 2) Failure of oral transmucosal fentanyl and 3) 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).



# NATPARA

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## Products Affected

- Natpara

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: 1) Medical record documentation of a diagnosis of hypocalcemia secondary to hypoparathyroidism and 2) Sufficient 25-hydroxyvitamin D stores and serum calcium (albumin adjusted) greater than 7.5 mg/dL before initiating therapy. Renewal criteria: 1) Reduction in symptoms and 2) maintenance of serum calcium concentration in the low-normal range.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Nephrologist or endocrinologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Failure of or intolerance to calcitriol.

# NERLYNX

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## Products Affected

- Nerlynx

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 or endocrinologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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.

# NEUPRO

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## Products Affected

- Neupro

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Documentation of an inability to swallow oral medications or failure of ropinirole and pramipexole.

# NORTHERA

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## Products Affected

- Northera

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal criteria: medical record documentation of treatment response including decrease in lightheadedness, dizziness or falls.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# NOXAFIL

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## Products Affected

- Noxafil

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Oropharyngeal candidiasis: 1 month. Prophylaxis of invasive fungal infections: 6 months.
<b>Other Criteria</b>	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.

# NUCALA

## Products Affected

- Nucala

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Age at least 12 years for asthma with eosinophilic phenotype.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a rheumatologist, pulmonologist, allergist or immunologist.
<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

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## Products Affected

- Nuedexta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	N/A

# NULOJIX

## Products Affected

- Nulojix

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation that Epstein-Barr virus status is positive.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Nephrologist or transplant specialist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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.

# Ocaliva

## Products Affected

- Ocaliva

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Used in combination with ursodeoxycholic acid (UDCA) unless there is documentation of intolerance. Renewal: 1) Alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal or a 15% decrease in ALP from baseline. 2) Continued use of ursodeoxycholic acid (UDCA) unless there is documentation of intolerance.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist or GI specialist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	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) dosed at 13-15 mg/kg or documented contraindication to UDCA.

# OCREVUS

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## Products Affected

- Ocrevus

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# ONFI

## Products Affected

- Onfi TABS 10MG, 20MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Age at least two.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Onfi must be used as adjunctive treatment. 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.

# ONFI SUSPENSION

## Products Affected

- Onfi SUSP

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Age at least two.
Prescriber Restrictions	N/A
Coverage Duration	Lifetime
Other Criteria	Onfi must be used as adjunctive treatment. 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 oral suspension: documentation of an inability to swallow solid dosage forms.

# OPSUMIT

## Products Affected

- Opsumit

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	<p>Initial: 1) Cardiac catheterization: mean Pulmonary Artery Pressure (mPAP) of at least 25 mmHg at rest, pulmonary capillary wedge pressure (PCWP) of less than 16 mmHg at rest, and World Health Organization (WHO) functional class II-IV, 2) if female and of childbearing age, use of reliable methods of birth control, 3) Baseline liver aminotransferases less than 3x ULN, and 4) Documented objective, measurable treatment goals to assess response to a 12-16 week trial such as an increase in the 6-minute walk test, or decrease in dyspnea fatigue rating and other symptoms, or evidence of improvement in hemodynamic mPAP or PVR or WHO class, or lack of functional or hemodynamic deterioration.</p> <p>Renewal: Monthly monitoring of LFTs and medical record documentation indicating objective treatment goals are met.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	Initial: 16 weeks. Renewal: 12 months.
<b>Other Criteria</b>	Failure of or contraindication to sildenafil and Tracleer (bosentan). Please note that both drugs require prior authorization.

## ORAL IMMUNOTHERAPY

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### Products Affected

- Grastek
- Ragwitek

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For Grastek: documentation of a positive skin test or pollen specific IgE antibodies to Timothy grass or cross-reactive grass pollens. For Ragwitek: documentation of a positive skin test or pollen specific IgE antibodies to short ragweed pollen.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Allergist or Immunologist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	N/A

## ORAL RIBAVIRIN

### Products Affected

- Moderiba TABS
- Ribasphere CAPS
- Ribasphere TABS 200MG
- Ribavirin CAPS
- Ribavirin TABS 200MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 1) 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance
<b>Other Criteria</b>	Ribavirin will be approved consistent with FDA approved labeling or AASLD/IDSA guidelines as part of treatment regimens consisting of Harvoni 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
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Not approved for use of acute or postoperative pain and for opioid non-tolerant patients.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist or Pain Specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Documentation of 1) Failure of two short-acting opioids (eg, oxycodone, morphine sulfate, etc) or if patient is unable to swallow, has 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

- Orenzia INJ 125MG/ML, 250MG

- Orenzia Clickject

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Rheumatoid arthritis and juvenile idiopathic arthritis 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.
<b>Age Restrictions</b>	JIA: age at least 6 years for Orenzia IV and age at least 2 years for Orenzia Subcutaneous Injection
<b>Prescriber Restrictions</b>	Rheumatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	1) For the treatment of rheumatoid arthritis, juvenile idiopathic arthritis and psoriatic arthritis: failure of Humira and Enbrel with prior authorization. 2) Not on concurrent therapy with another immune modulator such as Kineret (anakinra), Enbrel (etanercept), Humira (adalimumab) or infliximab.

# ORFADIN

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## Products Affected

- Orfadin CAPS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<i>Pending review</i>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	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.

# ORFADIN SUSPENSION

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## Products Affected

- Orfadin SUSP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Failure of Orfadin capsules or a reason why the capsules cannot be used.

# ORKAMBI

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## Products Affected

- Orkambi TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	<i>Pending review</i>
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# OXANDROLONE

## Products Affected

- Oxandrolone TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Carcinoma of the prostate or breast in males. 2) Carcinoma of the breast in females with hypercalcemia. 3) Hypercalcemia. 4) Nephrosis. 5) Pregnancy.
<b>Required Medical Information</b>	Wasting syndrome (weight loss/cachexia) Initial: 1) Weight loss of at least 10% and BMI less than 20 in the past 4 months. 2) Documentation of extensive surgery, chronic infection, long-term corticosteroid therapy, severe trauma, or some other condition that caused the member to not gain weight. Not covered for anorexia or weight loss alone. Renewal: Maintenance or increase in weight and BMI.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Wasting Syndrome: 6 months. All other diagnoses: 12 months.
<b>Other Criteria</b>	N/A

# OXYCODONE ER

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## Products Affected

- Oxycodone Hcl Er T12A
- Oxycontin T12A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Failure of sustained release morphine sulfate and not receiving concurrent therapy with another long-acting opioid, such as fentanyl or sustained release morphine sulfate.

# PALIFERMIN

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## Products Affected

- Kepivance

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	6 doses
<b>Other Criteria</b>	N/A



# PALYNZIQ

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## Products Affected

- Palynziq

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Phenylalanine level (Phe) at or above 600 micromol/L. Renewal: Reduction in Phe levels.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: Lifetime
<b>Other Criteria</b>	N/A

# PARENTERAL BISPHOSPHONATES

## Products Affected

- Pamidronate Disodium
- Zoledronic Acid
- Zometa INJ 4MG/100ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
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
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Hypercalcemia and vitamin D toxicity.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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.

# PAXIL SUSPENSION

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## Products Affected

- Paxil SUSP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The following criteria applies to members who newly start on the drug and are 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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

- Pegasys Proclick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist, infectious disease specialist, Hepatitis C specialist
<b>Coverage Duration</b>	HBV 12 mo. HCV: criteria will be applied consistent with current AASLD/IDSA guidance
<b>Other Criteria</b>	For the treatment of Hepatitis C, pegylated interferon is no longer standard of care. Refer to criteria for Mavyret, Epclusa, Harvoni and Vosevi.

# PRALUENT

## Products Affected

- Praluent

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial Criteria: A) Primary heterozygous familial hypercholesterolemia (HeFH): 1) Diagnosis confirmed by genetic mutation in the LDL receptor, ApoB or PCSK9 or clinical criteria using either the Simon Broom or WHO/Dutch Lipid Network criteria and 2) LDL-C greater than 130 mg/dL without ASCVD or greater than 100 mg/dL with ASCVD, and 3) documented drug failures as required in Other Criteria, and 4) will be used as adjunctive treatment to statin therapy unless contraindicated or the patient is unable to tolerate statins. B) Primary hypercholesterolemia and atherosclerotic cardiovascular disease (ASCVD): 1) diagnosis confirmed by acute coronary syndrome, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke or transient ischemic attack or peripheral arterial disease that is atherosclerotic in origin and 2) LDL-C greater than 100 mg/dL and 3) documented drug failures as required in Other Criteria and 4) will be used as adjunctive treatment to statin therapy unless contraindicated or the patient is unable to tolerate statins. Renewal Criteria: 1) continuance of adjunctive treatment with statin therapy unless contraindicated or the patient is unable to tolerate statins and 2) LDL reduction while on Praluent.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cardiologist, Endocrinologist or Lipid Specialist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	Medical record documentation of failure of one high-intensity statin therapy on the formulary (atorvastatin 40mg-80mg or rosuvastatin 20mg-40mg) for 12 weeks, or documented contraindications or significant side effects, or statin intolerance. Contraindications and significant side effects to statins include evidence of rhabdomyolysis or persistent myalgia or myositis.



# PRENATAL VITAMINS

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## Products Affected

- Vp-pnv-dha

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Male gender
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Age less 51 years.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A



# PREVYMIS

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## Products Affected

- Prevymis

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation that 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	100 days
<b>Other Criteria</b>	N/A

# PROLIA

## Products Affected

- Prolia

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For post-menopausal female with osteoporosis: 1) radiographic evidence of an osteoporotic fracture while on an oral bisphosphonate (alendronate, ibandronate or risedronate) or intranasal calcitonin-salmon or 2) high risk of fracture as defined by 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. For nonmetastatic prostate cancer receiving androgen deprivation therapy, breast cancer receiving adjuvant aromatase inhibitor therapy or males with osteoporosis: high risk of fracture as defined by one of the following: hip or vertebral fracture, T-score less than or equal to -2.5 at the femoral neck or spine after appropriate evaluation to exclude secondary causes, low bone mass (T-score between -1.0 and -2.5 at the femoral neck or spine) and a 10-year probability of a hip fracture greater than or equal to 3% or a 10-year probability of a major osteoporosis-related fracture greater than or equal to 20% based on the US-adapted WHO algorithm, or clinician's judgment and/or member preferences may indicate treatment for people with 10-year fracture probabilities above or below these levels.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For post-menopausal female with osteoporosis: failure of an oral bisphosphonate (alendronate, ibandronate or risedronate) or intranasal calcitonin-salmon. For nonmetastatic prostate cancer receiving androgen deprivation therapy, breast cancer receiving adjuvant aromatase inhibitor therapy or males with osteoporosis: failure of or contraindication to an oral bisphosphonates.

# PROMACTA

## Products Affected

- Promacta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<i>Pending review</i>
<b>Age Restrictions</b>	Age at least 1 year.
<b>Prescriber Restrictions</b>	For ITP: Hematologist or Oncologist. For hepatitis C, thrombocytopenia: Hematologist, GI specialist, Hepatologist or Oncologist. For aplastic anemia: Hematologist or Oncologist.
<b>Coverage Duration</b>	ITP: Initial 6wk, Renew 24wk. HepC, thrombo: Initial 3mo, Renew 12mo. AA: Initial 16 wk, Renew 6 mo.
<b>Other Criteria</b>	1) Chronic immune (idiopathic) thrombocytopenia refractory to the following: systemic corticosteroids and immunoglobulin replacement. 2) For the treatment of aplastic anemia: insufficient response to immunosuppressive therapy such as antithymocyte globulin (ATG) or cyclosporine.

## PULMONARY FIBROSIS AGENTS

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### Products Affected

- Esbriet
- Ofev

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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. Renewal criteria: medical record documentation of a decrease in the decline in force vital capacity (FVC).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# PURIXAN SUSPENSION

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## Products Affected

- Purixan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Documentation of an inability to swallow solid dosage forms.

# QUININE SULFATE

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## Products Affected

- Quinine Sulfate CAPS 324MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	7 days
<b>Other Criteria</b>	N/A

# RADICAVA

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## Products Affected

- Radicava

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist or a specialist in Amyotrophic Lateral Sclerosis (ALS)
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# RAVICTI

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## Products Affected

- Ravicti

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 1) Diagnosis confirmed by DNA testing and 2) Objective, measurable treatment goals are provided. Renewal: Medical record documentation of stabilization of disease progression such as stabilization of neurologic impairments or seizures.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Failure of Carbaglu and sodium phenylbutyrate powder.



# RECTIV

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## Products Affected

- Rectiv

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medical record documentation of chronic anal fissure lasting 4 or more weeks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	8 weeks.
<b>Other Criteria</b>	N/A

# REGRANEX

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## Products Affected

- Regranex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Neoplasm at the application site.
<b>Required Medical Information</b>	Renewal: documentation of a reduction in ulcer size by approximately 30% after 10 weeks of treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Surgeon, Podiatrist, Endocrinologist or Infectious Disease Specialist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 2 months.
<b>Other Criteria</b>	N/A

# RELISTOR

## Products Affected

- Relistor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Known or suspected mechanical gastrointestinal obstruction.
<b>Required Medical Information</b>	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. 2) Renewal for all indications: Documentation of a reduction in constipation measured objectively and abdominal pain.
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Advanced Illness: 4 months. All other indications: Initial 4 months, Renewal Lifetime.
<b>Other Criteria</b>	1) Failure of lactulose and polyethylene glycol 3350. 2) 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.

# REMODULIN

## Products Affected

- Remodulin

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Cardiac catheterization: mean Pulmonary Artery Pressure (mPAP) of at least 25 mmHg at rest, pulmonary capillary wedge pressure (PCWP) of less than 16 mmHg at rest, and New York Heart Association (NYHA) Class II to IV. Renewal: medical record documentation of treatment responses such as an increase in 6 minute walk test, decrease in dyspnea fatigue rating and other symptoms, evidence of hemodynamic improvement such as a reduction in mPAP and PVR or lack of functional decline
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	Initial: 16 weeks. Renewal: 12 months.
<b>Other Criteria</b>	Failure of or contraindication to sildenafil and Tracleer (bosentan). Please note that both drugs require prior authorization.

# RENFLEXIS

## Products Affected

- Renflexis

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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) Ulcerative Colitis (UC) Renewal: decrease in frequency of bloody stools and/or elimination of signs of toxicity. 3) Rheumatoid Arthritis (RA) Renewal: Improvement in number of tender, swollen joints, improved function, ability to perform ADLs and/or pain. 4) Psoriatic Arthritis (PsA) Renewal: Improved functioning and/or decreased in number of tender, swollen joints and reduction in skin lesions and/or has disease stability. 5) Ankylosing Spondylitis (AS) Renewal: Improved functioning: 6) Plaque psoriasis (PP) a) PP initial: duration of disease for at least 6 months covering more than 10% of body surface area or hand, foot or mucous membrane involvement. PP Renewal: improvement in affected BSA, plaque severity and/or functioning.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist or rheumatologist or dermatologist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.

<b>Other Criteria</b>	1) CD Initial: a) failure of or contraindication to an aminosalicyclic acid derivative and b) failure of or contraindication to methotrexate or azathioprine. 2) UC initial: a) failure of or contraindication to two of the following: aminosalicylates, prednisone, azathioprine or purinethol. 3) RA initial: a) failure of or contraindication to methotrexate and 2) failure of or contraindication to one other DMARD: leflunomide, cyclosporine, sulfasalazine, azathioprine or hydroxychloroquine and c) concurrent use with methotrexate unless contraindicated. 4) PsA Initial: a) failure of or contraindication to an oral NSAID and b) failure of or contraindication to methotrexate. 5) AS initial: a) failure of or contraindication to an oral NSAID. 6) PP initial: failure of or contraindication to methotrexate or cyclosporine. 7) For all diagnoses: not on concurrent therapy with another immune modulator such as abatacept, anakinra, etanercept, or adalimumab.
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# REPATHA

## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	<p>Initial Criteria: A) Primary heterozygous familial hypercholesterolemia (HeFH): 1) Diagnosis confirmed by genetic mutation in the LDL receptor, ApoB or PCSK9 or clinical criteria using either the Simon Broom or WHO/Dutch Lipid Network criteria and 2) LDL-C greater than 130 mg/dL without ASCVD or greater than 100 mg/dL with ASCVD, and 3) documented drug failures as required in Other Criteria, and 4) will be used adjunctive to statins unless contraindicated or the patient is unable to tolerate. B) Primary hypercholesterolemia: 1) Without atherosclerotic cardiovascular disease (ASCVD): a) LDL-C greater than 130 mg/dL, b) documented drug failures as required in Other Criteria, and c) will be used adjunctive to statins unless contraindicated or the patient is unable to tolerate. 2) With ASCVD: a) diagnosis confirmed by acute coronary syndrome, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke or transient ischemic attack or peripheral arterial disease that is atherosclerotic in origin and b) LDL-C greater than 100 mg/dL and c) documented drug failures as required in Other Criteria. C) Homozygous familial hypercholesterolemia (HoFH): 1) Diagnosis confirmed by a) two genetic mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 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. and 2) LDL-C greater than 130 mg/dL without ASCVD or greater than 100 mg/dL with ASCVD, and 3) documented drug failures as required in Other Criteria, and 4) will be used with statins and ezetimibe unless contraindicated or the patient is unable to tolerate. Renewal Criteria: 1) Continuance of treatment with statins unless contraindicated or the patient is unable to tolerate (except for ASCVD) and 2) LDL reduction while on Repatha.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	Cardiologist, Endocrinologist or Lipid Specialist
<b>Coverage Duration</b>	Initial: 6 months. Renewal: Lifetime.
<b>Other Criteria</b>	<p>A) For the treatment of HeFH and ASCVD: 1) Medical record documentation of failure of, documented contraindications or significant side effects on one high-intensity statin therapy on the formulary (atoravastatin 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. 2) Upon initial authorization and reauthorization: not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor such as Praluent. B) For the treatment of HoFH: 1) Medical record documentation of failure of, documented contraindications or significant side effects on one high-intensity statin therapy on the formulary (atoravastatin 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. 2) Medical record documentation of failure of ezetimibe in combination with a statin or reason why ezetimibe cannot be used. 3) Upon initial authorization and reauthorization: not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).</p>



# REXULTI

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## Products Affected

- Rexulti

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For the treatment of depression, Rexulti is being used with an antidepressant.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: 1) For the treatment of depression, failure of aripiprazole and olanzapine-fluoxetine. 2) For the treatment of schizophrenia, failure of two of the following: aripiprazole, ziprasidone, risperidone, olanzapine or quetiapine.

# RITUXAN

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## Products Affected

- Rituxan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Age at least 18 years.
<b>Prescriber Restrictions</b>	Oncologist or Rheumatologist
<b>Coverage Duration</b>	NHL, CLL, WG and MPA: Lifetime. RA Initial: 6 months. RA Renewal: 12 months.
<b>Other Criteria</b>	Rheumatoid arthritis (RA): Failure of two of the following immune modulators including abatacept, certolizumab, golimumab, etanercept, adalimumab, infliximab or anakinra.

# SABRIL

## Products Affected

- Sabril TABS

- Vigabatrin

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Complex Partial Seizures (CPS) Initial: Requires use with another anticonvulsant as combination therapy.
<b>Age Restrictions</b>	Infantile Spasm: age less than 2 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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.

# SANDOSTATIN LAR

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## Products Affected

- Sandostatin Lar Depot

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) For the treatment of acromegaly: medical record documentation of failure of surgery, radiation or bromocriptine or reason or reason why surgery, radiation or bromocriptine are not options. For the treatment of acromegaly, metastatic carcinoid tumors and vasoactive intestinal peptide tumors: documentation of response to and tolerance to octreotide immediate release injection.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# SHINGRIX

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## Products Affected

- Shingrix

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Age at least 50 years.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	2 doses given two to six months apart per lifetime.
<b>Other Criteria</b>	N/A

# SIGNIFOR

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## Products Affected

- Signifor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: Lifetime.
<b>Other Criteria</b>	N/A

# SILDENAFIL

## Products Affected

- Revatio SUSR

- Sildenafil TABS 20MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent therapy with nitrates.
<b>Required Medical Information</b>	Initial: 1) Cardiac catheterization: mean Pulmonary Artery Pressure (mPAP) of at least 25 mmHg at rest, pulmonary capillary wedge pressure (PCWP) of less than 16 mmHg at rest, and New York Heart Association (NYHA) Functional Class II-IV, and 2) Documentation of specific and measurable goals to assess response, such as significant increase in 6 minute walk test, decrease in dyspnea fatigue rating and other symptoms, evidence of hemodynamic improvement such as a reduction in mPAP and pulmonary vascular resistance (PVR) or lack of functional decline. Renewal: Predefined treatment goals are being met.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	Initial: 12 weeks. Renewal: 12 months.
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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 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 and/or elimination of signs of toxicity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Rheumatologist, dermatologist or gastroenterologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	1) RA initial: a) failure of or contraindication to methotrexate and at least one other DMARD such as leflunomide, cyclosporine, sulfasalazine, azathioprine, or hydroxychloroquine. 2) PsA Initial: a) failure of or contraindication to conventional management with at least one NSAID and methotrexate. 3) AS initial: a) failure of or contraindication to at least one NSAID. 4) UC Initial: failure of or contraindication to two of the following: aminosalicylates, prednisone, azathioprine or purinethol. 5) For all diagnoses: not on concurrent therapy with another immune modulator such as etanercept, abatacept, anakinra or infliximab.



# SIRTURO

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## Products Affected

- Sirturo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medical record documentation of 1) multi-drug resistance 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 and 3) Sirturo will be used in combination with 3 other drugs.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Infectious Disease or tuberculosis (TB) specialist
<b>Coverage Duration</b>	24 weeks
<b>Other Criteria</b>	N/A

# SOLTAMOX

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## Products Affected

- Soltamox

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant coumarin-type anticoagulant therapy or in women with a history of deep vein thrombosis or pulmonary embolus.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Documentation of an inability to take solid oral dosage forms.

# SOMATROPINS

## Products Affected

- Genotropin
- Genotropin Miniquick
- Humatrope INJ 12MG, 24MG, 6MG
- Humatrope Combo Pack
- Norditropin Flexpro
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Nutropin Aq Pen INJ 20MG/2ML
- Omnitrope
- Saizen
- Saizenprep Reconstitutionkit
- Zorbtive

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) In pediatric patients, evidence of closure of epiphyseal plate. 2) In patients with Prader-Willi syndrome, patients who are severely obese, have a history of upper airway obstruction, sleep apnea or severe respiratory impairment. 3) Not approved for the treatment of acute critical illness, respiratory failure or patients with an underlying intracranial tumor.
<b>Required Medical Information</b>	<i>Pending review</i>
<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

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## Products Affected

- Somatuline Depot

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For the treatment of acromegaly: medical record documentation of failure to surgery and/or radiotherapy or reason why surgery and/or radiotherapy are not options.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Baseline liver function tests are not greater than 3 times the upper limit of normal.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	5 years
<b>Other Criteria</b>	Failure or reason why the following cannot be used for treatment: a) surgery and/or radiotherapy and b) octreotide.

# SOTYLIZE

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## Products Affected

- Sotylize

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Medical record documentation of an inability to take solid oral dosage forms.

# SPRITAM

## Products Affected

- Spritam

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Evidence from documentation or claims history that Spritam is not being used as monotherapy for myoclonic seizures or primary generalized tonic-clonic seizures.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime.
<b>Other Criteria</b>	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, 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, 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.

# STRENSIQ

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## Products Affected

- Strensiq

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis confirmed by genetic testing, low serum activity of alkaline phosphatase or elevated pyridoxine.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist, Geneticist or Metabolic Specialist
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	N/A



# SUCRAID

## Products Affected

- Sucraid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist, Endocrinologist, Metabolic Specialist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Medical record documentation of intolerance to Orkambi (requires prior authorization).

# SYMLIN

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## Products Affected

- Symlinpen 120
- Symlinpen 60

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Hypoglycemia unawareness. 2) Gastroparesis.
<b>Required Medical Information</b>	Initial: a) HbA1c less than 9%.
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	<i>Pending review</i>

# SYMPROIC

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## Products Affected

- Symproic

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: Documentation of fewer than 3 spontaneous bowel movements per week and at least 25% of the bowel movements are associated with hard to very hard stools, moderate to very severe straining or sensation of incomplete evacuation. Renewal criteria: Documentation of a significant reduction in constipation measured objectively and abdominal pain.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Renewal: Lifetime.
<b>Other Criteria</b>	Failure of or contraindication to polyethylene glycol (PEG) and lactulose.

# SYNAGIS

## Products Affected

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

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

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<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

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## Products Affected

- Synarel

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Endometriosis: requires laparoscopic confirmation of diagnosis.
<b>Age Restrictions</b>	Central precocious puberty: Female age less than 11 years, Male age less than 12 years.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Endometriosis: 6 months. Central precocious puberty: female until age 11 and male until age 12.
<b>Other Criteria</b>	N/A

# TALTZ

## Products Affected

- Taltz

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1) Plaque psoriasis initial: duration of disease at least 6 months covering more than 5% of body surface area or hand, foot, face or genital involvement. 2) Plaque psoriasis renewal: improvement in affected body surface area, plaque severity and/or functioning. 3) 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
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For plaque psoriasis: dermatologist. For psoriatic arthritis: rheumatologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	1) For the treatment of plaque psoriasis: failure of Humira or Enbrel or contraindication to both. Humira and Enbrel require prior authorization. 2) For the treatment of psoriatic arthritis: failure of a) Humira or Enbrel with prior authorization and b) Cosentyx with prior authorization.



# TAVALISSE

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## Products Affected

- Tavalisse

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hematologist or Oncologist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months
<b>Other Criteria</b>	For chronic immune (idiopathic) thrombocytopenia: documentation of an insufficient response to a previous treatment such as: steroids, IVIG, Promacta, or Rituxan.

# TAZORAC

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## Products Affected

- Tazarotene CREA
- Tazarac CREA 0.05%
- Tazorac GEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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.

# TECFIDERA

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## Products Affected

- Tecfidera

- Tecfidera Starter Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Documentation that Tecfidera is being requested for monotherapy and is not intended to be used in combination with other multiple sclerosis agents.

# TEKTURNA

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## Products Affected

- Tekturna

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	Failure of one combination therapy with 2 of the following: thiazide diuretic, ACE inhibitor, angiotensin II receptor antagonist, and calcium channel blocker.

## TESTOSTERONE-SYSTEMIC

### Products Affected

- Methitest

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) Men with carcinoma of the breast. 2) Men with known or suspected carcinoma of the prostate.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For metastatic breast cancer: oncologist
<b>Coverage Duration</b>	Delayed puberty: 6 months. All other diagnoses: lifetime.
<b>Other Criteria</b>	N/A

# TETRABENAZINE

## Products Affected

- Tetrabenazine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	Neurologist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# THALOMID

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## Products Affected

- Thalomid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Erythema Nodosum Leprosum (ENL) Renewal criteria: documentation of response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	<i>Pending review</i>
<b>Coverage Duration</b>	Cancer: Lifetime. ENL: 12 months.
<b>Other Criteria</b>	N/A

## TOPICAL ANTIVIRALS

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### Products Affected

- Acyclovir OINT
- Denavir
- Zovirax CREA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	1) Failure of oral acyclovir and 2) For Denavir, failure of oral and topical acyclovir.



# TOPICAL TACROLIMUS

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## Products Affected

- Tacrolimus OINT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Renewal: reduction in number or severity of cutaneous lesions.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 weeks. Renewal: lifetime.
<b>Other Criteria</b>	Failure of two mid-to-high potency corticosteroids (eg. triamcinolone, betamethasone, fluocinonide, or clobetasol).

# TRANSDERM SCOP

## Products Affected

- Scopolamine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D and excessive salivation prophylaxis.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For members age 65 and older: 1) Documentation that the drug is being used for a FDA-approved indication and 2) The prescribing physician acknowledges that the requested drug is a high risk medication recommended to be avoided in the elderly and that the benefits of treatment outweighs the potential risks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Post-op nausea and vomiting: 1 dose. Motion sickness: 1 month. Excessive salivation: 12 months.
<b>Other Criteria</b>	For the treatment of motion sickness regardless of age: failure of or intolerance to meclizine.

# TRINTELLIX

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## Products Affected

- Trintellix

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Failure of 1) a selective serotonin reuptake inhibitor (SSRI): fluoxetine, paroxetine (requires prior authorization for members who newly start on paroxetine and are age 65 and older), citalopram, escitalopram, sertraline and 2) venlafaxine.

# TRUMENBA

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## Products Affected

- Trumenba

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Age 10-25 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Series of 3 doses
<b>Other Criteria</b>	N/A

# TYGACIL

## Products Affected

- Tigecycline

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	Infectious disease specialist
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	N/A

# TYMLOS

## Products Affected

- Tymlos

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	1) Postmenopausal female with either a) evidence of recent radiographic osteoporotic fracture while compliant on a bisphosphonate or b) high risk of osteoporotic fracture.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Up to a maximum of 24 months. Use is not recommended for longer.
<b>Other Criteria</b>	1) Failure of or contraindication to an oral bisphosphonate. 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
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	History of or existing progressive multifocal leukoencephalopathy.
<b>Required Medical Information</b>	Crohn's disease: 1) Baseline CRP greater than 2.87ml/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).
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	Neurologist or gastroenterologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	1) 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. 2) Crohn's disease: failure of infliximab and Humira.

# VARIZIG

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## Products Affected

- Varizig INJ 125UNIT/1.2ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	N/A



# VELTASSA

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## Products Affected

- Veltassa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: medical lab documentation of hyperkalemia. Renewal criteria: reduction in serum potassium from baseline.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Failure of one of the following: 1) a loop diuretic (torsemide, furosemide, bumetanide) or 2) a thiazide diuretic (hydrochlorothiazide or chlorothiazide).

# VENTAVIS

## Products Affected

- Ventavis

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial criteria: Initial: 1) Cardiac catheterization: mean Pulmonary Artery Pressure (mPAP) of at least 25 mmHg at rest, pulmonary capillary wedge pressure (PCWP) of less than 16 mmHg at rest, and New York Heart Association (NYHA) Class III to IV and 2) Documented objective, measurable treatment goals to assess response to a 12-16 week trial such as an increase in the 6-minute walk test, or decrease in dyspnea fatigue rating and other symptoms, or evidence of improvement in hemodynamic mPAP or PVR or NYHA class, or lack of functional or hemodynamic deterioration. Renewal: documentation that objective treatment goals are met.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or cardiologist
<b>Coverage Duration</b>	Initial: 16 weeks. Renewal: 12 months.
<b>Other Criteria</b>	Failure of or contraindication to sildenafil and Tracleer (bosentan). Please note that both drugs require prior authorization.

# VERSACLOZ

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## Products Affected

- Versacloz

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: Documentation of an inability to use clozapine oral disintegrating tablets.

# VIBERZI

## Products Affected

- Viberzi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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 one-month trial.
<b>Age Restrictions</b>	Age at least 18 years
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 12 weeks. Renewal: Lifetime.
<b>Other Criteria</b>	Failure of loperamide and dicyclomine.

# VIIBRYD

## Products Affected

- Viibryd TABS

- Viibryd Starter Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant use of a MAOI or within 14 days after discontinuing a MAOI.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	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 (requires prior authorization for members who newly start on paroxetine and are age 65 and older), fluoxetine, citalopram, escitalopram or sertraline and 2) venlafaxine.

# VOSEVI

## Products Affected

- Vosevi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: 1) Detectable HCV RNA (viral load), 2) Documentation of treatment history including response to previous treatment (treatment naive, 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance
<b>Other Criteria</b>	N/A

# VPRIV

## Products Affected

- Vpriv

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	Age 4 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	Dosing consistent with product label: 60 units/kg every other week. Range 15-60 units/kg.

# WELCHOL

## Products Affected

- Colesevelam Hydrochloride

- Welchol PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	1) History of bowel obstruction. 2) History of hypertriglyceridemia-induced pancreatitis. 3) Triglyceride levels greater than 500 mg/dL.
<b>Required Medical Information</b>	Diabetes Mellitus Renewal: documentation of an improvement in glycemic control such as a reduction from baseline in hemoglobin A1c.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Diabetes initial: 6 months. Diabetes renewal: lifetime. Hyperlipidemia: lifetime.
<b>Other Criteria</b>	For diabetes mellitus: 1) Failure of two of the following: metformin, a sulfonyleurea, a thiazolidinedione, or insulin. 3) Use of Welchol with metformin, a sulfonyleurea or insulin. For hyperlipidemia: failure of colestipol and cholestyramine.



# XERMELO

## Products Affected

- Xermelo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<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

# XGEVA

## Products Affected

- Xgeva

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Preexisting hypocalcemia and pregnancy.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	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

## Products Affected

- Xolair

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<i>Pending review</i>
<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
<b>Coverage Duration</b>	Asthma: Initial 12 weeks. Renewal 6 months. Urticaria: Initial 12 weeks. Renewal 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 with dose optimization for at least two weeks (failure defined as continued hives and itching). Formulary antihistamines include levocetirizine and desloratadine.

# XURIDEN

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## Products Affected

- Xuriden

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation of an endocrinologist or a metabolic specialist.
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 12 months.
<b>Other Criteria</b>	N/A

# XYREM

## Products Affected

- Xyrem

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

# ZAVESCA

## Products Affected

- Miglustat

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Initial: Medical record documentation of 1) Diagnostic conformation by biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts is less than or equal to 30% of normal activity or genotyping revealing two pathogenic mutations of the glucocerebrosidase gene, and 2) Hgb at least 9g/dL and platelet at least 50 x10 <sup>9</sup> /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

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### Products Affected

- Prolastin-c

- Zemaira

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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 between 30% to 65% 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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	Initial: 3 months. Renewal: 12 months.
<b>Other Criteria</b>	Initial: Medical record documentation of failure of or intolerance to Aralast or reason why Aralast cannot be used.

# ZINPLAVA

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## Products Affected

- Zinplava

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Evidence that the patient is currently using standard antibacterial drug treatment according to the FDA approved label.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 dose per 180 days
<b>Other Criteria</b>	N/A



# ZOSTAVAX

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## Products Affected

- Zostavax

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Age at least 50 years.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 dose
<b>Other Criteria</b>	Reason why Shingrix cannot be used such as a reaction or allergy to the vaccine or immediate vaccination is required and Shingrix is unavailable.

# ZYPREXA RELPREVV

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## Products Affected

- Zyprexa Relprevv

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Lifetime
<b>Other Criteria</b>	The following criteria applies to members who newly start on the drug: 1) Currently taking oral olanzapine and prescriber wishes to switch to the injection to improve compliance or 2) Failure of or intolerance to Risperdal Consta.

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU
- Ambisome
- Aminosyn INJ 148MEQ/L;  
1280MG/100ML; 980MG/100ML;  
1280MG/100ML; 300MG/100ML;  
720MG/100ML; 940MG/100ML;  
720MG/100ML; 400MG/100ML;  
440MG/100ML; 5.4MEQ/L;  
860MG/100ML; 420MG/100ML;  
520MG/100ML; 160MG/100ML;  
44MG/100ML; 800MG/100ML,  
90MEQ/L; 1100MG/100ML;  
850MG/100ML; 35MEQ/L;  
1100MG/100ML; 260MG/100ML;  
620MG/100ML; 810MG/100ML;  
624MG/100ML; 340MG/100ML;  
380MG/100ML; 5.4MEQ/L;  
750MG/100ML; 370MG/100ML;  
460MG/100ML; 150MG/100ML;  
44MG/100ML; 680MG/100ML
- Aminosyn 7%/electrolytes
- Aminosyn 8.5%/electrolytes
- Aminosyn II INJ 61.1MEQ/L;  
844MG/100ML; 865MG/100ML;  
595MG/100ML; 627MG/100ML;  
425MG/100ML; 255MG/100ML;  
561MG/100ML; 850MG/100ML;  
893MG/100ML; 146MG/100ML;  
253MG/100ML; 614MG/100ML;  
450MG/100ML; 33.3MEQ/L;  
340MG/100ML; 170MG/100ML;  
230MG/100ML; 425MG/100ML,  
71.8MEQ/L; 993MG/100ML;  
1018MG/100ML; 700MG/100ML;  
738MG/100ML; 500MG/100ML;  
300MG/100ML; 660MG/100ML;  
1000MG/100ML; 1050MG/100ML;  
172MG/100ML; 298MG/100ML;  
722MG/100ML; 530MG/100ML;  
38MEQ/L; 400MG/100ML;  
200MG/100ML; 270MG/100ML;  
500MG/100ML
- Aminosyn II 8.5%/electrolytes
- Aminosyn M INJ 65MEQ/L;  
448MG/100ML; 343MG/100ML;  
40MEQ/L; 448MG/100ML;  
105MG/100ML; 252MG/100ML;  
329MG/100ML; 252MG/100ML;  
3MEQ/L; 140MG/100ML;  
154MG/100ML; 3.5MMOLE/L;  
13MEQ/L; 300MG/100ML;  
147MG/100ML; 40MEQ/L;  
182MG/100ML; 56MG/100ML;  
31MG/100ML; 280MG/100ML
- Aminosyn-hbc

- Aminosyn-pf INJ 46MEQ/L; 698MG/100ML; 1227MG/100ML; 527MG/100ML; 820MG/100ML; 385MG/100ML; 312MG/100ML; 760MG/100ML; 1200MG/100ML; 677MG/100ML; 180MG/100ML; 427MG/100ML; 812MG/100ML; 495MG/100ML; 3.4MEQ/L; 70MG/100ML; 512MG/100ML; 180MG/100ML; 44MG/100ML; 673MG/100ML
- Aminosyn-pf 7%
- Aminosyn-rf
- Amphotec
- Amphotericin B INJ
- Azasan
- Azathioprine INJ
- Azathioprine TABS
- Bleomycin INJ 30UNIT
- Bleomycin Sulfate INJ 30UNIT
- Brovana
- Budesonide SUSP
- Cladribine
- Clinimix 2.75%/dextrose 5%
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 20%
- Clinimix 4.25%/dextrose 25%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 5%/dextrose 25%
- Clinimix E 2.75%/dextrose 10%
- Clinimix E 2.75%/dextrose 5%
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 25%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 5%/dextrose 25%
- Clinimix N14g30e
- Clinisol Sf 15%
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine INJ
- Cyclosporine Modified
- Cytarabine Aqueous
- Deltasone TABS 20MG
- Depo-medrol INJ 20MG/ML
- Engerix-b
- Freamine Hbc 6.9%
- Freamine III INJ 89MEQ/L; 710MG/100ML; 950MG/100ML; 3MEQ/L; 24MG/100ML; 1400MG/100ML; 280MG/100ML; 690MG/100ML; 910MG/100ML; 730MG/100ML; 530MG/100ML; 560MG/100ML; 10MMOLE/L; 120MG/100ML; 1120MG/100ML; 590MG/100ML; 10MEQ/L; 400MG/100ML; 150MG/100ML; 660MG/100ML
- Ganciclovir INJ 500MG
- Gengraf
- Hepatamine
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Methotrexate TABS
- Methylprednisolone TABS
- Methylprednisolone Acetate INJ 40MG/ML, 80MG/ML
- Methylprednisolone Sodiumsuccinate INJ 1000MG, 125MG, 40MG
- Mycophenolate Mofetil
- Mycophenolic Acid Dr
- Nebupent
- Nephramine
- Nutrilipid
- Ondansetron Hcl ORAL SOLN
- Ondansetron Hcl TABS
- Ondansetron Odt
- Plenamine
- Prednisone SOLN

- Prednisone TABS 10MG, 1MG, 2.5MG, 20MG, 50MG, 5MG
- Premasol
- Procalamine
- Prograf INJ
- Prosol
- Pulmozyme
- Rabavert
- Rapamune SOLN
- Recombivax Hb
- Simulect
- Sirolimus TABS
- Solu-medrol INJ 2GM, 500MG
- Tacrolimus CAPS
- Tobramycin NEBU
- 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; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Trexall
- Trophamine INJ 97MEQ/L; 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
- Twinrix
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ
- Xatmep
- Zortress

## 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.

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