

PRIOR AUTHORIZATION PROTOCOLS

How do I request an exception to the Ultimate Health Plans' Formulary?

You can ask Ultimate Health Plans to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary.
- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, Ultimate Health Plans limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover more.
- You can ask us to provide a higher level of coverage for your drug. If your drug is contained in our non-preferred tier, you can ask us to cover it at the cost-sharing amount that applies to drugs in the preferred tier instead. This would lower the amount you must pay for your drug. Please note, if we grant your request to cover a drug that is not on our formulary, you may not ask us to provide a higher level of coverage for the drug. "Also, you may not ask us to provide a higher level of coverage for drugs that are in the specialty tier."

Generally, Ultimate Health Plans will only approve your request for an exception if the alternative drugs included on the plan's formulary, the lower-tiered drug or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, tiering or utilization restriction exception. **When you are requesting a formulary, tiering or utilization restriction exception you should submit a statement from your physician supporting your request.** Generally, we must make our decision within 72 hours of getting your prescribing physician's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get your prescribing physician's supporting statement.

Your physician must submit a statement supporting your coverage determination or exception request. In order to help us make a decision more quickly, you should include supporting medical information from your doctor when you submit your exception request.

What if I have additional questions?

You can call us at: 1-800-546-5677 (seven days a week, 24 hours a day) if you have any additional questions. If you have a hearing or speech impairment, please call us at TTY 1-866-706-4757.

ABSTRAL

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ACTEMRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA.

AGE RESTRICTIONS:

MD RESTRICTIONS: RA (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION: End of plan year.

OTHER CRITERIA: RA (Reauth): Documentation of positive clinical response to Actemra therapy. Patient is not receiving Actemra in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

ADCIRCA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ADEMPAS

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Pregnancy category X—Patient must not be pregnant.

REQUIRED INFO:

AGE RESTRICTIONS: Patient is 18 years of age or older.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ALOSETRON HYDROCHLORIDE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of severe, chronic, diarrhea-predominant irritable bowel syndrome (IBS) in women who have failed conventional therapy.

EXCLUSION CRITERIA: 1) Men are not eligible for treatment. 2) Patients should not have severe hepatic disease or impairment. 3) Patients with ischemic colitis, constipation, gastrointestinal disease, Crohn's disease, ulcerative colitis, or diverticulitis.

REQUIRED INFO: 1) Patient has diagnosis of irritable bowel syndrome with diarrhea being the main problem. 2) Prescriber attests that patient has read and signed the Patient-Physician Agreement for Lotronex. 3) Physician has ruled-out anatomic or biochemical abnormalities of the gastrointestinal tract. 4) Patient should be an adult female. 5) Patient has failed or has a contraindication to conventional therapies for diarrhea treatment.

AGE RESTRICTIONS: Patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

AMPHETAMINE/DEXTROAMPHETA

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

AMPYRA

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Covered indications include treatment of multiple sclerosis to improve walking.
- EXCLUSION CRITERIA:** 1) Patients with renal insufficiency and a creatinine clearance less than or equal to 50mL per min. 2) Patients with a history of seizures or a seizure disorder.
- REQUIRED INFO:** 1) Patient must be ambulatory. 2) A baseline serum creatinine must be obtained prior to initiation of medication.
- AGE RESTRICTIONS:** Patients must be greater than or equal to 18 years of age.
- MD RESTRICTIONS:** Medication must be prescribed by a neurologist or MS specialist.
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

ANADROL-50

COVERED USES: All FDA-approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA: In patients with nephrosis or the nephrotic phase of nephritis. In patients with severe hepatic dysfunction. Carcinoma of the prostate or breast in male patients. Carcinoma of the breast in females with hypercalcemia. Pregnancy in females of reproductive potential.

REQUIRED INFO: Anadrol-50 will not be used as replacement of other supportive measures, e.g., correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, etc., if any

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

APOKYN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Apomorphine is used to treat "off" episodes when they occur. It is not used to prevent "off" episodes. The safety and efficacy has not been established for use in pediatrics. Pregnancy category is C. The patient must have a diagnosis of Parkinson's disease, Acute, intermittent treatment of hypomobility "off" episodes.

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ARALAST NP

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Alpha-1-antitrypsin deficiency

EXCLUSION CRITERIA:

REQUIRED INFO: Patients must be immunized against Hepatitis B prior to receiving Aralast.

AGE RESTRICTIONS: Patient must be at least 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ARANESP ALBUMIN FREE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Treatment of patients who require immediate correction of severe anemia - Treatment of anemia in cancer or HIV-infected patients caused by other factors such as iron or folate deficiencies, hemolysis or GI bleeding. In these cases the underlying cause of the anemia should be managed appropriately - Treatment of anemia in rheumatoid arthritis - Treatment of pruritis associated with renal failure - Treatment of anemia in Gaucher's disease - Treatment of anemia in Castleman's disease - Treatment of anemia in paroxysmal nocturnal hemoglobinuria (PNH) - Treatment of sickle cell anemia - Treatment of symptomatic anemia related to zidovudine therapy in HIV-infected patients where the dose of zidovudine is -Less Than- 4200 mg/week - Treatment of anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery or patients at high risk for perioperative transfusions with significant, anticipated blood loss - Myelodysplastic syndrome in patients whose pre-treatment endogenous erythropoietin level is - Less Than- 500 mU/ml - Anemia of prematurity, when the patient has either a birthweight -Less Than- 1500 grams or a gestational age of -Less Than- 33 weeks - Special circumstance patients (such as Jehovah Witness) who will not/cannot receive whole blood or components as replacement for traumatic or surgical loss. Uncontrolled hypertension.

REQUIRED INFO: This medication must not meet the criteria for coverage under Medicare Part A or B. Treatment of symptomatic anemia associated with chronic renal failure, including patients on dialysis (end-stage renal disease) and patients not on dialysis OR anemia in cancer patients receiving chemotherapy. Pretreatment hemoglobin levels must be less than 10 g/dL. Medication is prescribed to achieve and maintain hemoglobin of 10 g/dL for adults with CKD not on dialysis or with cancer, 11 g/dL for adults with CKD on dialysis, or 12 g/dL for children with CKD.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ARCALYST

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of cryopyrin-associated periodic syndromes (CAPS) including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome.

EXCLUSION CRITERIA: Patient may not take Arcalyst while on etanercept, infliximab, adalimumab or anakinra.

REQUIRED INFO:

AGE RESTRICTIONS: Patients must be greater than or equal to 12 years of age

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ARMODAFINIL

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

AUBAGIO

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** 1) Patient must not be using in combination with leflunomide and 2) patient must not have severe hepatic impairment.
- REQUIRED INFO:** 1) Baseline liver function tests or clinical notes documenting patient does not have severe hepatic impairment and 2) for female patient's of childbearing potential only: a) patient must have a negative pregnancy test result within 2 weeks prior to start of therapy and b) documentation must be provided that patient is using reliable contraception.
- AGE RESTRICTIONS:** Patient is at least 18 years of age.
- MD RESTRICTIONS:** Prescribed by or in consult with a neurologist or MS specialist.
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

AVONEX

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and proceeded by stability or improvement for at least 30 days. The patient must have a diagnosis of or Multiple Sclerosis (MS), Relapsing Multiple Sclerosis, Relapsing-Remitting Multiple Sclerosis (RRMS) and Progressive - Relapsing Multiple Sclerosis.

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

AVONEX PEN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and proceeded by stability or improvement for at least 30 days. The patient must have a diagnosis of or Multiple Sclerosis (MS), Relapsing Multiple Sclerosis, Relapsing-Remitting Multiple Sclerosis (RRMS) and Progressive - Relapsing Multiple Sclerosis.

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

BENLYSTA

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

BERINERT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (e.g., Firazyr, Kalbitor, or Ruconest).

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION: End of plan year.

OTHER CRITERIA:

BETASERON

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and preceded by stability or improvement for at least 30 days. The patient must have a diagnosis of or Multiple Sclerosis (MS) or Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

BIVIGAM

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

CARIMUNE NANOFILTERED

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

CARISOPRODOL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: For patients less than or equal to 64 years, claim will automatically pay. For patients greater than or equal to 65 years, coverage determination is approved for FDA-approved indications not otherwise excluded from Part D, AND prescriber must acknowledge that medication benefit outweighs potential risks.

AGE RESTRICTIONS: Less than or equal to 64 years old, claim for target drug automatically pays. Greater than or equal to 65 years old, prior authorization exception request is required indicating medically accepted indication not otherwise excluded from Part D.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

CAYSTON

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include to improve respiratory symptoms in cystic fibrosis patients with *Pseudomonas aeruginosa*.

EXCLUSION CRITERIA:

REQUIRED INFO: Documentation must be provided with evidence of *Pseudomonas aeruginosa* lung infection.

AGE RESTRICTIONS: Patients must be at least 7 years of age.

MD RESTRICTIONS: Medication is being prescribed by a pulmonologist, endocrinologist, or infectious disease specialist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

CERDELGA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Gaucher disease (Initial): Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.

AGE RESTRICTIONS: 18 years of age and older

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year.

OTHER CRITERIA: Gaucher disease (Reauth): Patient's condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) liver volume increased greater than 20% from baseline.

CHOLBAM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient has liver disease , steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets).

AGE RESTRICTIONS:

MD RESTRICTIONS: All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.

COVERAGE DURATION: End of plan year.

OTHER CRITERIA:

CIALIS

COVERED USES: All FDA-Approved indication not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

CICLOPIROX NAIL LACQUER

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

CIMZIA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include to reduce signs and symptoms and to maintain clinical response in patients with moderately to severely active Crohn's disease who have an inadequate response to conventional therapy, and the treatment of moderately to severely active rheumatoid arthritis

EXCLUSION CRITERIA:

REQUIRED INFO: 1) A negative tuberculosis skin test must be obtained prior to treatment initiation. 2) Patients being treated for Crohn's disease should have a documented failure to a salicylate (mesalamine, sulfasalazine), an oral corticosteroid, or an immunomodulator (azathioprine, methotrexate) and Humira.

AGE RESTRICTIONS: Patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

CINRYZE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: HAE Prophylaxis: Diagnosis of HAE. Prescribed for prophylaxis against HAE attacks. Trial, failure, intolerance, or contraindication to an attenuated (17-alpha alkylated) androgen (e.g. danazol) also indicated for HAE prophylaxis.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION: End of plan year.

OTHER CRITERIA:

CLARAVIS

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
1. Patients must have a diagnosis of severe recalcitrant nodular or cystic acne and have evidence of scarring or 2. Severe disfiguring cystic acne that is recalcitrant to standard therapies.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

CORLANOR

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: FDA labeled contraindication(s) to the requested agent

REQUIRED INFO: Criteria for approval require ALL of the following: 1) Patient has stable, symptomatic chronic heart failure (e.g. NYHA Class II, III, IV, ACCF/AHA Class C, D) AND 2) Patient has a baseline OR current left ventricular ejection fraction of less than or equal to 35% AND 3) Patient is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute AND 4) ONE of the following: A) Patient is on a maximally tolerated dose of beta blocker (e.g. atenolol, bisoprolol, carvedilol, metoprolol) OR B) Patient has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to a beta blocker

AGE RESTRICTIONS: NA

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

COSENTYX

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment.

AGE RESTRICTIONS: Patient is at least 18 years of age.

MD RESTRICTIONS: Prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Patient has tried and failed at least one nonbiologic therapy (e.g. methotrexate, topical corticosteroid, calcipotriene, tazarotene, anthralin, acetretin, cyclosporine, topical tacrolimus, topical pimecrolimus) AND has tried Humira.

COSENTYX SENSOREADY PEN

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment.

AGE RESTRICTIONS: Patient is at least 18 years of age.

MD RESTRICTIONS: Prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Patient has tried and failed at least one nonbiologic therapy (e.g. methotrexate, topical corticosteroid, calcipotriene, tazarotene, anthralin, acetretin, cyclosporine, topical tacrolimus, topical pimecrolimus) AND has tried Humira.

CRINONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Use in patients to supplement or replace progesterone as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency.

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year.

OTHER CRITERIA:

CYSTARAN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation AND Patient is concomitantly receiving treatment with oral cysteamine.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year.

OTHER CRITERIA:

DALIRESP

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the prevention of COPD exacerbations in patients with severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and a history of exacerbations.
- EXCLUSION CRITERIA:** 1) Patients with moderate to severe hepatic impairment. 2) Patients experiencing acute bronchospasms. Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.
- REQUIRED INFO:** Baseline liver function tests should be obtained prior to treatment initiation.
- AGE RESTRICTIONS:** Patients must be greater than or equal to 18 years of age.
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

DARAPRIM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Toxoplasmosis: 1) Patient is using Daraprim for the treatment of toxoplasmic encephalitis, toxoplasmosis chorioretinitis, or congenital toxoplasmosis OR 2) Patient is using Daraprim for the primary prophylaxis of toxoplasmosis following a hematopoietic stem cell transplant, or secondary prophylaxis of toxoplasmosis encephalitis.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with an infectious disease specialist

COVERAGE DURATION: End of plan year.

OTHER CRITERIA: Toxoplasmosis only: Approve for continuation of prior therapy.

DEXMETHYLPHENIDATE HCL

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

DEXMETHYLPHENIDATE HCL ER

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

DEXTROAMPHETAMINE SULFATE

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

DICLOFENAC SODIUM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Osteoarthritis: 1) Must be used for signs and symptoms of osteoarthritis of the knee(s) AND 2) Must have therapeutic failure with a one-week trial of an oral NSAID OR pt has had intolerable side effects or contraindications to oral NSAIDs.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year.

OTHER CRITERIA:

DRONABINOL

COVERED USES: All FDA-approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

EGRIFTA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: HIV-associated lipodystrophy (initial): All of the following: 1) diagnosis of HIV-associated lipodystrophy, 2) one of the following: a) waist-circumference of at least 95 cm (37.4 inches) AND waist-to-hip ratio of at least 0.94 in men, OR b) waist-circumference of at least 94 cm (37 inches) AND waist-to-hip ratio of at least 0.88 in women.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year.

OTHER CRITERIA: (reauth): documentation of clinical improvement (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc.) while on Egrifta therapy.

ENBREL

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: shall not be granted for use Wegener's granulomatosis.

REQUIRED INFO: patient with a diagnosis of plaque psoriasis must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following, Topical corticosteroid, Tazarotene, Anthralin. Patient with a diagnosis of either rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following disease modifying antirheumatic drugs (DMARDs), Methotrexate, Hydroxychloroquine, D-penicillamine, Sulfasalazine, Leflunomide, Azathioprine, Oral/Injectable Gold Compounds.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ENBREL SURECLICK

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: shall not be granted for use Wegener's granulomatosis.

REQUIRED INFO: patient with a diagnosis of plaque psoriasis must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following, Topical corticosteroid, Tazarotene, Anthralin. Patient with a diagnosis of either rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following disease modifying antirheumatic drugs (DMARDs), Methotrexate, Hydroxychloroquine, D-penicillamine, Sulfasalazine, Leflunomide, Azathioprine, Oral/Injectable Gold Compounds.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ENTRESTO

- COVERED USES:** All FDA-approved indications not otherwise excluded from Part D. Indicated for the treatment of CHF (NYHA Class II, III, or IV, with reduced left ventricular ejection fraction.)
- EXCLUSION CRITERIA:** CHF NYHA Class I LVEF greater than 40%. FDA labeled contraindications
- REQUIRED INFO:** Documentation of Left ventricular ejection fraction less than or equal to 40%. Documentation of CHF diagnosis and NYHA classification II, III, or IV
- AGE RESTRICTIONS:**
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:**

EPCLUSA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Documentation of chronic hepatitis C infection and genotype.
Documentation of quantitative baseline HCV RNA load.

AGE RESTRICTIONS: Patient is at least 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Criteria will be applied consistent with current AASLD/IDSA guidance. Patient had a trial of Harvoni for genotypes 1, 4, 5 or 6 or patient meets one of the following: 1) patient had a documented severe intolerance or hypersensitivity to Harvoni OR 2) patient has a contraindication to Harvoni such as receiving concurrent interacting drug therapy.

ESBRIET

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

EXJADE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
1. Chronic iron toxicity. 2. Chronic iron toxicity secondary to transfusional iron overload.

EXCLUSION CRITERIA: Exjade will not be covered if the serum creatinine is greater than 2 times the age-appropriate upper limit of normal (ULN), creatinine clearance is less than 40 mL/min, patient has poor performance status, patient has high-risk myelodysplastic syndrome (MDS), patient has advanced malignancy, or patient has a platelet count less than $50 \times 10^9/L$.

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

EXTAVIA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and preceded by stability or improvement for at least 30 days. The patient must have a diagnosis of or Multiple Sclerosis (MS) or Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

FENTANYL CITRATE ORAL TRA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Breakthrough cancer pain in opioid tolerant patients with malignancies currently taking chronic pain medications

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

FERRIPROX

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: 1) Serum iron studies confirming iron overload. 2) Patient has tried Exjade with inadequate response.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

FIRAZYR

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of Plan year

OTHER CRITERIA: NA

FLEBOGAMMA DIF

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

FORTEO

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Postmenopausal osteoporosis in women who are at a high risk for fracture, Primary osteoporosis in men, Hypogonadal osteoporosis in men, glucocorticoid-induced osteoporosis in patients at high risk of fracture.

EXCLUSION CRITERIA: Forteo shall not be approved for any of the following reasons: in children or adolescents, Paget's disease of the bone, hypercalcemia, patients with bone cancer or other cancers that have metastasized to the bones

REQUIRED INFO: The patient should also meet National Osteoporosis Foundation guidelines for treatment and have one of the following: 1. Bone Mineral Density (BMD) 2.5 or more standard deviations below the mean value (ie T-score less than 2.5) with no risk factors OR 2. BMD T-score below 1.5 (1.5 or more standard deviations below the mean value) with one or more risk factors 3. Prior vertebral or hip fracture 4. Patients must also have a prior failure or intolerance to at least one of the following therapies: Bisphosphonate (Fosamax, Actonel, Boniva), Miacalcin, Evista (SERM)

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GAMMAGARD LIQUID

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GAMMAGARD S/D IGA LESS TH

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GAMMAKED

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GAMMAPLEX

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GAMUNEX-C

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GATTEX

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: 1) Patient is dependent on parenteral support. 2) Colonoscopy of the entire colon has been performed within 6 months prior to starting initial treatment.

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GENOTROPIN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

GENOTROPIN MINIQUICK

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

GLASSIA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Alpha-1-antitrypsin deficiency

EXCLUSION CRITERIA:

REQUIRED INFO: Patients must be immunized against Hepatitis B prior to receiving Zemaira.

AGE RESTRICTIONS: Approved in patients 18 years of age and older for alpha-1 proteinase inhibitor (A1PI) deficiency.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GLATIRAMER ACETATE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The patient must have had an inadequate response or a documented failure due to lack of efficacy to interferon beta 1. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GLATOPA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The patient must have had an inadequate response or a documented failure due to lack of efficacy to interferon beta 1. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

GRANIX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, 2) patient is receiving chemotherapy regimen following bone marrow transplant, OR 2) both of the following: a) patient receiving chemotherapy regimen with 10-20% risk of FN AND b) patient has any of the following FN risk factors: 1) 65 years of age or older 2) prior chemo or radiation therapy 3) persistent neutropenia 4) HIV 5) CrCL below 50 mL/min 5) bilirubin level greater than 2 mg/dL 6) recent surgery or open wounds 7) bone marrow involvement by tumor

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist

COVERAGE DURATION: End of plan year.

OTHER CRITERIA:

H.P. ACTHAR

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HETLIOZ

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HUMATROPE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

HUMATROPE COMBO PACK

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

HUMIRA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira (adalimumab).

AGE RESTRICTIONS: Patient must be at least 2 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HUMIRA PEDIATRIC CROHNS D

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira (adalimumab).

AGE RESTRICTIONS: Patient must be at least 2 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HUMIRA PEN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira (adalimumab).

AGE RESTRICTIONS: Patient must be at least 2 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HUMIRA PEN-CD/UC/HS START

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira (adalimumab).

AGE RESTRICTIONS: Patient must be at least 2 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HUMIRA PEN-CROHNS DISEASE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira (adalimumab).

AGE RESTRICTIONS: Patient must be at least 2 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HUMIRA PEN-PS/UV STARTER

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira (adalimumab).

AGE RESTRICTIONS: Patient must be at least 2 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

HUMIRA PEN-PSORIASIS STAR

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must not have an active infection (chronic or acute). The patient has a negative TB test result prior to therapy. The patient is not receiving anakinra (Kineret), etanercept (Enbrel), or infliximab (Remicade) in combination with Humira (adalimumab).

AGE RESTRICTIONS: Patient must be at least 2 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ITRACONAZOLE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of invasive aspergillosis including invasive pulmonary, CNS, and cutaneous aspergillosis, as well as Aspergillus sinusitis, tracheobronchitis, endocarditis, pericarditis, myocarditis, osteomyelitis, infectious arthritis, and aspergilloma in patients who are intolerant of or refractory to amphotericin B therapy, blastomycosis treatment, histoplasmosis treatment, the treatment of onychomycosis due to dermatophytes (tinea unguium) in immunocompetent patients, mucocutaneous candidiasis treatment, and the treatment of aspergillus eye infections.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

JADENU

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Chronic Iron Overload Due to Non-Transfusion Dependent Thalassemia (NTDT)(Initial): Diagnosis of NTDT. Patient has serum ferritin level greater than 300 mcg/L AND liver iron concentration of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).

AGE RESTRICTIONS: Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older

MD RESTRICTIONS: Prescribed by or in consultation with a hematologist/oncologist, hepatologist, or infectious disease specialist

COVERAGE DURATION: End of plan year.

OTHER CRITERIA: Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin lev

JADENU SPRINKLE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Chronic Iron Overload Due to Non-Transfusion Dependent Thalassemia (NTDT)(Initial): Diagnosis of NTDT. Patient has serum ferritin level greater than 300 mcg/L AND liver iron concentration of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).

AGE RESTRICTIONS: Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older

MD RESTRICTIONS: Prescribed by or in consultation with a hematologist/oncologist, hepatologist, or infectious disease specialist

COVERAGE DURATION: End of plan year.

OTHER CRITERIA: Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin lev

JUXTAPID

- COVERED USES:** All FDA approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** 1) Patient has moderate or severe hepatic impairment (Child-Pugh category B or C) or active hepatic disease. 2) Patient is pregnant.
- REQUIRED INFO:** 1) Patient has a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia defined as a) documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality OR b) skin fibroblast LDL receptor activity less than 20% normal, OR c) untreated TC greater than 500 mg/dL and TG less than 300 mg/dL and both parents with documented untreated TC greater 250 mg/dL. 2) Baseline liver function tests.
- AGE RESTRICTIONS:** Patient must be at least 18 years old.
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

KEVEYIS

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Severe pulmonary disease, hepatic insufficiency, concomitant use of high-dose aspirin

REQUIRED INFO: For primary HYPOkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) patient has a family history of primary hypokalemic periodic paralysis, OR 3) patients attacks are associated with hypokalemia AND both Andersen-Tawil syndrome and thyrotoxic periodic paralysis have been ruled out. For primary HYPERkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) patient has a family history of primary hyperkalemic periodic paralysis, OR 3) patients attacks are associated with hyperkalemia AND Andersen-Tawil syndrome has been ruled out.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Initial: 2 months. Continuation: 12 months.

OTHER CRITERIA: Keveyis is used as maintenance therapy to prevent attacks. For continuation of therapy, patient is demonstrating a response to Keveyis therapy as demonstrated by a decrease in the number of attacks.

KINERET

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** Prior authorization requests shall not be granted for use in multiple sclerosis, lupus erythematosus, juvenile rheumatoid arthritis, inflammatory bowel diseases, sepsis syndrome or graft-versus-host disease. Kineret should not be used in combination with Tumor Necrosis Factor (TNF) blocking agents (Enbrel, Remicade). Kineret should also not be used in patients with active infections.
- REQUIRED INFO:** For the diagnosis of RA, the patient must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following disease modifying antirheumatic drugs (DMARDs), such as: Methotrexate--Hydroxychloroquine--D-penicillamine--Sulfasalazine--Leflunomide--Azathioprine--Oral/Injectable Gold Compounds (auranofin, aurothioglucose, gold sodium thiomalate). The patient must not be using Kineret in combination with Enbrel, Remicade, or Humira. For the diagnosis of RA, the patient must have a diagnosis of moderately to severely active rheumatoid arthritis (RA) as defined by the American College of Rheumatology (ACR).
- AGE RESTRICTIONS:** For the diagnosis of RA, the patient must be at least 18 years of age
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

KORLYM

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Patient is pregnant.

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS: Medication is being prescribed by an endocrinologist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

KUVAN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) in conjunction with a phenylalanine (Phe)-restricted diet.

EXCLUSION CRITERIA:

REQUIRED INFO: 1) A baseline phenylalanine level must be obtained prior to treatment initiation.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

KYNAMRO

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Patient has moderate or severe hepatic impairment (Child-Pugh category B or C) or active hepatic disease.

REQUIRED INFO: 1) Patient has a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia defined as either a) LDLR DNA sequence analysis showing two mutant alleles OR b) history of untreated LDL cholesterol over 500 mg/dL with either tendinous and/or cutaneous xanthoma prior to age 10 years or documentation of elevated LDL cholesterol over 190 mg/dL prior to lipid-lowering therapy consistent with HeFH in both parents. In cases where a parent is not available, a history of coronary artery disease in a first degree male relative of the parent younger than 55 years or first degree female relative of the parent younger than 60 years is acceptable. 2) Baseline liver function tests. 3) Patient is on other lipid-lowering treatment.

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

LETAIRIS

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Pulmonary arterial hypertension, WHO Group I.

EXCLUSION CRITERIA:

REQUIRED INFO: None.

AGE RESTRICTIONS: Safety and effectiveness not established in pediatric patients

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Available only through the Letairis Education Access Program (LEAP) by calling 1-866-664-LEAP (5327) or by logging on to www.letairis.com.

LIDOCAINE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Topical local anesthetic to skin

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

LUPANETA PACK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Endometriosis (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID or one oral contraceptive.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

MENEST

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: For patients less than or equal to 64 years, claim will automatically pay. For patients greater than or equal to 65 years, coverage determination is approved for FDA-approved indications not otherwise excluded from Part D, AND prescriber must acknowledge that medication benefit outweighs potential risks.

AGE RESTRICTIONS: Less than or equal to 64 years old, claim for target drug automatically pays. Greater than or equal to 65 years old, prior authorization exception request is required indicating medically accepted indication not otherwise excluded from Part D.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

METADATE ER

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

METHITEST

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG), and b) one pretreatment calculated free or bioavailable T level less than 5 ng/dL (0.17nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG. Delayed Puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG , and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

METHYLPHENIDATE HCL

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

METHYLPHENIDATE HCL CD

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

METHYLPHENIDATE HCL ER

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

METHYLPHENIDATE HCL ER (L)

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

METHYLPHENIDATE HYDROCHLO

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

METHYLTESTOSTERONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG), and b) one pretreatment calculated free or bioavailable T level less than 5 ng/dL (0.17nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG. Delayed Puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG , and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

MIGLUSTAT

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of mild to moderate type 1 Gaucher's disease in patients for whom enzyme replacement therapy is not an option.

EXCLUSION CRITERIA: 1) Patients with renal dysfunction and a creatinine clearance less than or equal to 30mL per min.

REQUIRED INFO: 1) A baseline serum creatinine must be obtained prior to treatment initiation.

AGE RESTRICTIONS: Patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

MIRVASO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Diagnosis of rosacea. Patient has moderate to severe persistent (nontransient) facial erythema.

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Documentation of positive clinical response for reauthorization of Mirvaso.

MODAFINIL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 17 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

MYALEPT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND Patient is refractory to current standards of care for lipid and diabetic management AND One or more of the following metabolic abnormalities are present: A) Insulin resistance (defined as requiring more than 200 units per day), B) Hypertriglyceridemia, or C) Diabetes

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline

MYORISAN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
1. Patients must have a diagnosis of severe recalcitrant nodular or cystic acne and have evidence of scarring or 2. Severe disfiguring cystic acne that is recalcitrant to standard therapies.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

NATPARA

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Patient is well-controlled on calcium supplements and vitamin D alone.

REQUIRED INFO: 1) Baseline serum calcium level.

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

NEULASTA

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** Prior Authorization request shall not be granted for use in patient receiving chemotherapy associated with delayed myelosuppression. Prior Authorization request shall not be granted for use in patient with neutropenia other than chemotherapy-related.
- REQUIRED INFO:** The patient must have had an inadequate response or a documented failure due to lack of efficacy to one or more of the following colony stimulating factors. Such as: Filgrastim, Neulasta must not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Neulasta 6mg fixed-dose formulation must not be used in infants, children, and adolescents weighing less than 45 kg. Febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs. 6mg subcutaneous injection once per chemotherapy cycle.
- AGE RESTRICTIONS:**
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

NEUPOGEN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Neutropenia secondary to chemotherapy--Bone marrow transplantation--Idiopathic, cyclic, or congenital neutropenia, Peripheral blood progenitor cell (PBPC) mobilization or Post-PBPC transplantation, AIDS-associated neutropenia, Drug-induced neutropenia, Myelodysplastic syndromes complicated with infection

EXCLUSION CRITERIA:

REQUIRED INFO: Prior authorizations will only be approved for patients who will be self-administering filgrastim. Patients that receive their injections in the provider's office or from home health care should have the filgrastim covered under their medical benefit. Appropriate lab tests - CBC and platelet count, must be conducted to necessitate the continuation of therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

NORDITROPIN FLEXPRO

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

NORTHERA

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Neurogenic orthostatic hypotension is caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy.

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

NUEDEXTA

- COVERED USES:** All FDA-approved indications not otherwise excluded from Part D. Pseudobulbar affect in adults.
- EXCLUSION CRITERIA:** Patient does not have a diagnosis of heart failure. Patient does not have a diagnosis of complete atrioventricular (AV) block without an implanted pacemaker.
- REQUIRED INFO:** Patient has had a baseline electrocardiographic (ECG) evaluation to rule out QT prolongation or prescriber indicates that patient is not at risk for QT prolongation.
- AGE RESTRICTIONS:** Patient is 18 years of age or older.
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

NUTROPIN AQ NUSPIN 10

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

NUTROPIN AQ NUSPIN 20

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

NUTROPIN AQ NUSPIN 5

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

OCALIVA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND Ocaliva will used in combination with UDCA, OR b) contraindication or intolerance to UDCA.

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS: Prescribed by or in consultation with a hepatologist or gastroenterologist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pretreatment baseline (ie, prior Ocaliva therapy) while on Ocaliva therapy.

OCTAGAM

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

OCTREOTIDE ACETATE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Acromegaly, Carcinoid tumors, Vasoactive Intestinal Peptide Tumors (VIPomas).

EXCLUSION CRITERIA:

REQUIRED INFO: The patient must tolerate an initial treatment of Sandostatin® Injectable for a minimum of 2 weeks.

AGE RESTRICTIONS: The patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

OFEV

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

OMNITROPE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

OPSUMIT

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Patient is pregnant.

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ORENCIA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: May use drug as monotherapy or concomitantly with DMARD except TNF antagonist or other biologic rheumatoid arthritis agents (eg. Anakinra).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ORENCIA CLICKJECT

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: May use drug as monotherapy or concomitantly with DMARD except TNF antagonist or other biologic rheumatoid arthritis agents (eg. Anakinra).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ORENITRAM

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Patient must not have severe hepatic impairment (Child Pugh class C).

REQUIRED INFO: 1) Baseline liver function tests or clinical notes documenting patient does not have severe hepatic impairment and 2) patient has a diagnosis of pulmonary arterial hypertension (PAH: WHO group I) verified by right sided heart catheterization.

AGE RESTRICTIONS: Patient is at least 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

OTEZLA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. PsA, plaque psoriasis (initial): Trial and failure, contraindication, or intolerance to both Humira and Enbrel, OR for continuation of prior Otezla therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS: PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION: Initial, Reauth: 12 months

OTHER CRITERIA: Reauthorization (all indications): Documentation of positive clinical response to Otezla therapy.

OXANDROLONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Promote weight gain (initial): Medication will be used as an adjunct therapy to promote weight gain AND One of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons. Counterbalance protein catabolism (initial): Oxandrin will be used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain (initial): Diagnosis of bone pain associated with osteoporosis.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: All diagnoses (reauth): patient has experienced an objective improvement (i.e. weight gain, increase in lead body mass, or reduction in muscle pain/weakness)

PALYNZIQ

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient must have a baseline blood phenylalanine concentration greater than 600 micromol/L prior to initiation.

AGE RESTRICTIONS: 18 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

PLEGRIDY

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

PLEGRIDY STARTER PACK

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

PRALUENT

- COVERED USES:** All FDA-approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** Patient is receiving concomitant therapy with another PCSK9 inhibitor
- REQUIRED INFO:** Most recent cholesterol laboratory report. Heterozygous Familial Hypercholesterolemia: medical records supporting clinical or laboratory confirmation of diagnosis: A) genetic confirmation of a mutation in LDL receptor, ApoB, or PCSK9, B) score of 6 or higher on the Dutch Lipid Network criteria for HeFH, C) presence of xanthomas with pretreatment LDL greater than 190 mg/dL. Hypercholesterolemia: documented history of clinical atherosclerotic cardiovascular disease (defined as acute coronary syndrome, history of myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other revascularization, clinically significant coronary heart disease, or peripheral arterial disease of atherosclerotic origin.
- AGE RESTRICTIONS:** Patient is at least 18 years of age.
- MD RESTRICTIONS:** Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist.
- COVERAGE DURATION:** Initial: 3 months. Renewal: End of plan year.
- OTHER CRITERIA:** For statin tolerant patients: 1) Must have a therapeutic failure to a 3 month trial of maximally tolerated dose of high intensity statin therapy with at least two different statin medications (i.e. atorvastatin 40mg or 80mg, simvastatin 40mg or 80mg, rosuvastatin 20mg or 40mg) with failure to achieve LDL-C less than 100 mg/dL AND 2) patient must continue statin therapy unless unable to tolerate statins. Intolerance to statins or contraindication to statins: 1) Patient has an intolerance to statin therapy including severe and intolerable adverse effects with at least two previous statins such as increased liver function tests, rhabdomyolysis, intolerable myalgia, myopathy or myositis or patient has a contraindication to statin therapy. Reauthorization requests require 1) documentation of continued statin use if applicable and 2) documented LDL reduction from baseline.

PRIVIGEN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

PROCRIT

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: 1. Treatment of patients who require immediate correction of severe anemia -

REQUIRED INFO: 1. Treatment of symptomatic anemia associated with chronic renal failure, including patients on dialysis (end-stage renal disease) and patients not on dialysis. 2. Treatment of symptomatic anemia where erythropoietin level is -Less Than- 500 mU/ml, related to zidovudine therapy in HIV-infected patients where the dose of zidovudine is -Less Than- 4200 mg/week. 3. Treatment of symptomatic anemia in patients with non-myeloid malignancies and anemia is caused by the effect of administered chemotherapy and the patient must be on chemotherapy concomitantly for a minimum of 2 months. 4. Treatment of anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Special circumstance patients (such as Jehovah Witness) who will not/cannot receive whole blood or components as replacement for traumatic or surgical loss will be taken into consideration.

PROLASTIN-C

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Alpha-1-antitrypsin deficiency

EXCLUSION CRITERIA:

REQUIRED INFO: Patients must be immunized against Hepatitis B prior to receiving Zemaira.

AGE RESTRICTIONS: Approved in patients 18 years of age and older for alpha-1 proteinase inhibitor (A1PI) deficiency.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

PROLIA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: 1) Patients with hypocalcemia.

REQUIRED INFO: 1) When using Prolia for osteoporosis in men and women at high risk for bones fractures with nonmetastatic prostate cancer or breast cancer, must provide evidence that men have been receiving androgen deprivation therapy (surgical castration or medical castration with GnRH agonist, GnRH antagonists, or anti-androgens) and women have been receiving adjuvant aromatase inhibitor therapy. 2) When using Prolia for postmenopausal osteoporosis in women with high fracture risk, patient must meet criteria for having high fracture risk including one of the following-history of osteoporotic fracture, family history of fracture, low body mass index, rheumatoid arthritis, use of corticosteroids, anticonvulsants, or loop diuretics, increased fall risk (poor vision, dementia, neuromuscular disorder), low bone mineral density with a T-score of -2.5 or lower, age greater than or equal to 50 years of age, current smoker, or alcohol intake greater than or equal to 3 drinks per day. 3) A baseline calcium level must be obtained prior to treatment initiation.

AGE RESTRICTIONS: Patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

PROMACTA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patients must be greater than or equal to 1 year of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

PULMOZYME

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the management of cystic fibrosis in conjunction with standard therapies, to improve pulmonary function.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patients must be greater than or equal to 5 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

QUININE SULFATE

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

RAVICTI

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Ravicti is prescribed for treatment of acutely elevated ammonia concentrations in a patient with urea cycle disorders.

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

REBIF

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The patient must have the ability to self-administer the medication. Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and proceeded by stability or improvement for at least 30 days. Has had baseline CBC and LFT lab tests. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

REBIF REBIDOSE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The patient must have the ability to self-administer the medication. Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and proceeded by stability or improvement for at least 30 days. Has had baseline CBC and LFT lab tests. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

REBIF REBIDOSE TITRATION

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The patient must have the ability to self-administer the medication. Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and proceeded by stability or improvement for at least 30 days. Has had baseline CBC and LFT lab tests. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

REBIF TITRATION PACK

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The patient must have the ability to self-administer the medication. Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and proceeded by stability or improvement for at least 30 days. Has had baseline CBC and LFT lab tests. The patient must have a diagnosis of Relapsing-Remitting Multiple Sclerosis (RRMS).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

REGRANEX

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. The patient must have a diagnosis of a lower extremity diabetic neuropathic ulcer.
- EXCLUSION CRITERIA:** Prior authorization requests shall not be granted for use in pressure ulcers.
- REQUIRED INFO:** The ulcer must extend into the subcutaneous tissue or beyond. (Stage III or IV as defined by the International Association of Enterostomal Therapy for staging chronic wounds). The patient must have failed standard therapy for at least two months (careful and frequent debridement, moist dressing changes, and non-weight bearing). The ulcer must have an adequate blood supply.
- AGE RESTRICTIONS:**
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

RELISTOR

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: 1) Patient is receiving opioids. 2) Patient has an advanced illness and receiving palliative care OR patient has chronic noncancer pain. 3) For patients with advanced illness receiving palliative care, patient has failed or has an intolerance to one other conventional laxative therapy.

AGE RESTRICTIONS: Patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

REPATHA

- COVERED USES:** All FDA-approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** Patient is receiving concomitant therapy with another PCSK9 inhibitor
- REQUIRED INFO:** Most recent cholesterol laboratory report. Heterozygous Familial Hypercholesterolemia: medical records supporting clinical or laboratory confirmation of diagnosis: A) genetic confirmation of a mutation in LDL receptor, ApoB, or PCSK9, B) score of 6 or higher on the Dutch Lipid Network criteria for HeFH, C) presence of xanthomas with pretreatment LDL greater than 190 mg/dL for adults or 155 mg/dL in children less than 16 years old. Hyperlipidemia: documented history of clinical atherosclerotic cardiovascular disease (defined as acute coronary syndrome, history of myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other revascularization, clinically significant coronary heart disease, or peripheral arterial disease of atherosclerotic origin. Homozygous Familial Hypercholesterolemia: A) Pre-treatment LDL greater than 500 mg/dL OR B) genetic testing confirming 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein OR C) treated LDL greater than 300 mg/dL with presence of either xanthomas prior to age 10 years or untreated elevated LDL in both parents consistent with HeFH.
- AGE RESTRICTIONS:** Patient is at least 13 years of age for HoFH. Patient is at least 18 years of age for HeFH or hyperlipidemia with atherosclerotic cardiovascular disease.
- MD RESTRICTIONS:** Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist.
- COVERAGE DURATION:** Initial: 3 months. Renewal: End of plan year.
- OTHER CRITERIA:** For statin tolerant patients: 1) Must have a therapeutic failure to a 3 month trial of maximally tolerated dose of high intensity statin therapy with at least two different statin medications (i.e. atorvastatin 40mg or 80mg, simvastatin 40mg or 80mg, rosuvastatin 20mg or 40mg) with failure to achieve LDL-C less than 100 mg/dL AND 2) patient must continue statin therapy unless unable to tolerate statins. Intolerance to statins or contraindication to statins: 1) Patient has an intolerance to statin therapy including severe and intolerable adverse effects with at least two previous statins such as increased liver function tests, rhabdomyolysis, intolerable myalgia, myopathy or myositis or patient has a contraindication to statin therapy AND for HoFH only 2) patient must also demonstrate

REPATHA

therapeutic failure to a 3 month trial of ezetimibe. Reauthorization requests require 1) documentation of continued statin use if applicable and 2) documented LDL reduction from baseline.

REPATHA PUSHTRONEX SYSTEM

- COVERED USES:** All FDA-approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** Patient is receiving concomitant therapy with another PCSK9 inhibitor
- REQUIRED INFO:** Most recent cholesterol laboratory report. Heterozygous Familial Hypercholesterolemia: medical records supporting clinical or laboratory confirmation of diagnosis: A) genetic confirmation of a mutation in LDL receptor, ApoB, or PCSK9, B) score of 6 or higher on the Dutch Lipid Network criteria for HeFH, C) presence of xanthomas with pretreatment LDL greater than 190 mg/dL for adults or 155 mg/dL in children less than 16 years old. Hyperlipidemia: documented history of clinical atherosclerotic cardiovascular disease (defined as acute coronary syndrome, history of myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other revascularization, clinically significant coronary heart disease, or peripheral arterial disease of atherosclerotic origin. Homozygous Familial Hypercholesterolemia: A) Pre-treatment LDL greater than 500 mg/dL OR B) genetic testing confirming 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein OR C) treated LDL greater than 300 mg/dL with presence of either xanthomas prior to age 10 years or untreated elevated LDL in both parents consistent with HeFH.
- AGE RESTRICTIONS:** Patient is at least 13 years of age for HoFH. Patient is at least 18 years of age for HeFH or hyperlipidemia with atherosclerotic cardiovascular disease.
- MD RESTRICTIONS:** Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist.
- COVERAGE DURATION:** Initial: 3 months. Renewal: End of plan year.
- OTHER CRITERIA:** For statin tolerant patients: 1) Must have a therapeutic failure to a 3 month trial of maximally tolerated dose of high intensity statin therapy with at least two different statin medications (i.e. atorvastatin 40mg or 80mg, simvastatin 40mg or 80mg, rosuvastatin 20mg or 40mg) with failure to achieve LDL-C less than 100 mg/dL AND 2) patient must continue statin therapy unless unable to tolerate statins. Intolerance to statins or contraindication to statins: 1) Patient has an intolerance to statin therapy including severe and intolerable adverse effects with at least two previous statins such as increased liver function tests, rhabdomyolysis, intolerable myalgia, myopathy or myositis or patient has a contraindication to statin therapy AND for HoFH only 2) patient must also demonstrate

REPATHA PUSHTRONEX SYSTEM

therapeutic failure to a 3 month trial of ezetimibe. Reauthorization requests require 1) documentation of continued statin use if applicable and 2) documented LDL reduction from baseline.

REPATHA SURECLICK

- COVERED USES:** All FDA-approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** Patient is receiving concomitant therapy with another PCSK9 inhibitor
- REQUIRED INFO:** Most recent cholesterol laboratory report. Heterozygous Familial Hypercholesterolemia: medical records supporting clinical or laboratory confirmation of diagnosis: A) genetic confirmation of a mutation in LDL receptor, ApoB, or PCSK9, B) score of 6 or higher on the Dutch Lipid Network criteria for HeFH, C) presence of xanthomas with pretreatment LDL greater than 190 mg/dL for adults or 155 mg/dL in children less than 16 years old. Hyperlipidemia: documented history of clinical atherosclerotic cardiovascular disease (defined as acute coronary syndrome, history of myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other revascularization, clinically significant coronary heart disease, or peripheral arterial disease of atherosclerotic origin. Homozygous Familial Hypercholesterolemia: A) Pre-treatment LDL greater than 500 mg/dL OR B) genetic testing confirming 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein OR C) treated LDL greater than 300 mg/dL with presence of either xanthomas prior to age 10 years or untreated elevated LDL in both parents consistent with HeFH.
- AGE RESTRICTIONS:** Patient is at least 13 years of age for HoFH. Patient is at least 18 years of age for HeFH or hyperlipidemia with atherosclerotic cardiovascular disease.
- MD RESTRICTIONS:** Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist.
- COVERAGE DURATION:** Initial: 3 months. Renewal: End of plan year.
- OTHER CRITERIA:** For statin tolerant patients: 1) Must have a therapeutic failure to a 3 month trial of maximally tolerated dose of high intensity statin therapy with at least two different statin medications (i.e. atorvastatin 40mg or 80mg, simvastatin 40mg or 80mg, rosuvastatin 20mg or 40mg) with failure to achieve LDL-C less than 100 mg/dL AND 2) patient must continue statin therapy unless unable to tolerate statins. Intolerance to statins or contraindication to statins: 1) Patient has an intolerance to statin therapy including severe and intolerable adverse effects with at least two previous statins such as increased liver function tests, rhabdomyolysis, intolerable myalgia, myopathy or myositis or patient has a contraindication to statin therapy AND for HoFH only 2) patient must also demonstrate

REPATHA SURECLICK

therapeutic failure to a 3 month trial of ezetimibe. Reauthorization requests require 1) documentation of continued statin use if applicable and 2) documented LDL reduction from baseline.

REVATIO

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: 1.NPS will not grant any PAs for sildenafil 20mg tablet if the diagnosis is for erectile dysfunction. 2. Member must not be concurrently taking a nitrate, ritonavir, or an alpha adrenergic blocker (i.e. doxazosin, prazosin, terazosin, phenoxybenzamine, tamsulosin).

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: A caution was issued for sildenafil use with any alpha blocker.

RILUZOLE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. RILUTEK is indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: The safety and the effectiveness of RILUTEK in pediatric patients have not been established.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

RUCONEST

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, or Kalbitor).

AGE RESTRICTIONS:

MD RESTRICTIONS: HAE: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

SAIZEN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

SAIZENPREP RECONSTITUTION

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

SEROSTIM

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Adolescent Growth Failure (783.43). Growth Failure. Adult patients with documented GHD (253.2, 253.3, 253.7) secondary to destructive lesions of the pituitary or the peripituitary area (e.g., pituitary adenoma), or as a result of treatment (e.g., cranial irradiation) or surgery. Adult patients with idiopathic growth hormone deficiency (783.43), Growth retardation in children with chronic renal insufficiency (593.9, 585.2-585.9), Patients with Turner's syndrome (758.6). GH therapy for patients with Turner's syndrome, Patients with AIDS (042) related wasting with involuntary weight loss, Children with Russel – Silver syndrome (759.89), Short Stature in Children with Noonan's syndrome—Norditropin® (759.89), Children with Prader – Willi syndrome.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.

SIGNIFOR

COVERED USES: All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cushing's disease - pituitary surgery is not an option or has not been curative. Acromegaly - patient had an inadequate response to surgery and/or surgery is not an option.

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

SILDENAFIL

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: 1.NPS will not grant any PAs for sildenafil 20mg tablet if the diagnosis is for erectile dysfunction. 2. Member must not be concurrently taking a nitrate, ritonavir, or an alpha adrenergic blocker (i.e. doxazosin, prazosin, terazosin, phenoxybenzamine, tamsulosin).

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: A caution was issued for sildenafil use with any alpha blocker.

SIMPONI

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be 18 years of age or older.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

SIMVASTATIN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient has been taking simvastatin 80 mg per day chronically (12 months or more) and no evidence of muscle toxicity/myopathy (eg, muscle pain, muscle tenderness, muscle weakness) on simvastatin 80 mg per day.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

SOMAVERT

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patients have had a documented inadequate response to surgery and/or radiation therapy. Patient must have baseline LFTs (AST and ALT less than 3 times upper limit). Patients must have failed ONE or MORE of the following treatments: Transsphenoidal surgery, Radiation therapy, Octreotide, Lanreotide, Bromocriptine. Diagnosis of acromegaly documented by elevated GH levels (GH level -Greater Than- 5ng/mL)

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

SOVALDI

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

SPORANOX

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of invasive aspergillosis including invasive pulmonary, CNS, and cutaneous aspergillosis, as well as Aspergillus sinusitis, tracheobronchitis, endocarditis, pericarditis, myocarditis, osteomyelitis, infectious arthritis, and aspergilloma in patients who are intolerant of or refractory to amphotericin B therapy, blastomycosis treatment, histoplasmosis treatment, the treatment of onychomycosis due to dermatophytes (tinea unguium) in immunocompetent patients, mucocutaneous candidiasis treatment, and the treatment of aspergillus eye infections.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

SYMLINPEN 120

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: 1) Patients with gastroparesis. 2) Patients with hemoglobin A1C greater than or equal to 9 percent.

REQUIRED INFO: 1) Treatment must be adjunct to insulin therapy. 2) Must obtain a baseline Hemoglobin A1C prior to treatment initiation.

AGE RESTRICTIONS: Patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

SYMLINPEN 60

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: 1) Patients with gastroparesis. 2) Patients with hemoglobin A1C greater than or equal to 9 percent.

REQUIRED INFO: 1) Treatment must be adjunct to insulin therapy. 2) Must obtain a baseline Hemoglobin A1C prior to treatment initiation.

AGE RESTRICTIONS: Patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

TALTZ

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTIONS: Patient must be at least 18 years old

MD RESTRICTIONS: Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Plaque psoriasis (Reauth): Documentation of positive clinical response to Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

TAZORAC

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acne vulgaris (initial): Diagnosis of acne vulgaris AND History of failure or intolerance to at least two topical acne products (e.g., tretinoin, adapalene, benzoyl peroxide, clindamycin, erythromycin, or azelaic acid). Plaque psoriasis (initial): Diagnosis of stable moderate to severe plaque psoriasis AND Patient has body surface area (BSA) involvement of less than 20 percent AND History of failure or intolerance to at least two topical psoriasis product (e.g., medium to high potency corticosteroids and/or vitamin D analogs).

AGE RESTRICTIONS: Acne (initial): Patient must be at least 12 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Acne, Plaque psoriasis (reauth): Documentation of positive clinical response to therapy .

TECFIDERA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient is at least 18 years of age.

MD RESTRICTIONS: Prescribed by or in consult with a neurologist or MS specialist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

TECFIDERA STARTER PACK

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Patient is at least 18 years of age.

MD RESTRICTIONS: Prescribed by or in consult with a neurologist or MS specialist.

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

TECHNIVIE

- COVERED USES:** All FDA-approved indications not otherwise excluded from Part D.
- EXCLUSION CRITERIA:** Patient has moderate or severe hepatic impairment (Child-Pugh B or C).
- REQUIRED INFO:** Documentation of chronic hepatitis C infection and genotype.
Documentation of quantitative baseline HCV RNA load.
- AGE RESTRICTIONS:** Patient is at least 18 years old.
- MD RESTRICTIONS:** Prescribed by or in consultation with an infectious disease specialist or hepatology/gastroenterology specialist.
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:**

TETRABENAZINE

- COVERED USES:** All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of chorea associated with Huntington's Disease (Huntington's Chorea).
- EXCLUSION CRITERIA:** Patients with hepatic impairment.
- REQUIRED INFO:** Baseline liver function tests should be obtained prior to treatment initiation.
- AGE RESTRICTIONS:** Patients must be greater than or equal to 18 years of age.
- MD RESTRICTIONS:**
- COVERAGE DURATION:** End of plan year
- OTHER CRITERIA:** NA

UPTRAVI

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient has a diagnosis of pulmonary arterial hypertension (PAH: WHO group I) verified by right sided heart catheterization.

AGE RESTRICTIONS: Patient is at least 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

VENTAVIS

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Pulmonary hypertensive arterial disease

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS: Safety and efficacy in pediatric patients have not been established

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

VIVITROL

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Alcohol dependence, maintenance of abstinence

EXCLUSION CRITERIA: Patients must not have acute hepatitis or liver failure. Patient must not have an opioid dependency or acute opiate withdrawal. Patient must not be taking opioid analgesics as concomitant therapy

REQUIRED INFO:

AGE RESTRICTIONS: Patients must be at least 18 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

XGEVA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

XIFAXAN

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D. Covered indications include the treatment of patients with traveler's diarrhea caused by noninvasive strains of Escherichia coli and for reducing the risk of overt hepatic encephalopathy recurrence.

EXCLUSION CRITERIA: Patient's with Clostridium Difficile associated diarrhea.

REQUIRED INFO:

AGE RESTRICTIONS: 1) For traveler's diarrhea, patients must be greater than or equal to 12 years of age. 2) For hepatic encephalopathy prophylaxis, patients must be greater than or equal to 18 years of age.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

XIIDRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Initial: Diagnosis of dry eye disease. Patient has suppressed tear production due to ocular inflammation as determined by at least one of the following diagnostic tests: Schirmer test (aqueous tear production and clearance), tear break-up time, ocular surface dye staining, tear film osmolarity, or fluorescein clearance test/tear function test.

AGE RESTRICTIONS: Patient must be at least 17 years old

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Reauth: Documentation of positive clinical response to Xiidra therapy (e.g., increased tear production or improvement in dry eye symptoms).

XYREM

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Cataplexy associated with narcolepsy

EXCLUSION CRITERIA: The patient is not concurrently taking any sedative hypnotic agents at the time of the prior authorization review

REQUIRED INFO:

AGE RESTRICTIONS: Patient must be at least 18 years old.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ZARXIO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm³), AND 2) patients with a history of Febrile Neutropenia (FN) during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm³), AND 2) patients with FN at high risk for infection-associated complications.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by hematologist/oncologist or infectious disease specialist

COVERAGE DURATION: End of plan year

OTHER CRITERIA: Documentation of positive clinical response for reauthorization of Zarxio.

ZEMAIRA

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
Alpha-1-antitrypsin deficiency

EXCLUSION CRITERIA:

REQUIRED INFO: Patients must be immunized against Hepatitis B prior to receiving Zemaira.

AGE RESTRICTIONS: Approved in patients 18 years of age and older for alpha-1 proteinase inhibitor (A1PI) deficiency.

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ZENATANE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.
1. Patients must have a diagnosis of severe recalcitrant nodular or cystic acne and have evidence of scarring or 2. Severe disfiguring cystic acne that is recalcitrant to standard therapies.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA

ZENZEDI

COVERED USES: All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS: NA

COVERAGE DURATION: End of plan year

OTHER CRITERIA:

ZORBTIVE

COVERED USES: All FDA-Approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: End of plan year

OTHER CRITERIA: NA