

ACTEMRA

MEDICATION(S)

ACTEMRA 162 MG/0.9 ML SYRINGE

COVERED USES

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

EXCLUSION CRITERIA

Active infection, live vaccines, concomitant use with biological Disease Modifying Anti-Rheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION

Documented diagnosis of Adult Rheumatoid Arthritis (RA), Giant Cell Arteritis (GCA), or Polyarticular Juvenile Idiopathic Arthritis (PJIA). For RA and PJIA: Documentation that patient had a trial or inadequate response to at least one DMARD OR is intolerant to DMARDs (such as sulfasalazine, leflunomide, hydroxychloroquine, methotrexate). Documentation of inadequate response or inability to tolerate one tumor necrosis factor antagonist (such as Enbrel or Humira). For all diagnoses: Documented evaluation of tuberculosis (TB), hepatitis B, and active infection. Lab results must be attached: absolute neutrophil count (ANC), platelet count, aspartate transaminase (AST) and alanine transaminase (ALT).

AGE RESTRICTION

2 years of age and older for PJIA. 18 years of age and older for RA and GCA.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with a Rheumatologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

ACTIQ (FENTANYL LOZENGE)

MEDICATION(S)

FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

COVERED USES

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

EXCLUSION CRITERIA

Prescribers and patients not enrolled in TIRF REMs Access Program. Must not be used in opioid non-tolerant patients.

REQUIRED MEDICAL INFORMATION

For use in the management of breakthrough pain in cancer patients (documentation must be attached) who are already receiving and have become tolerant to around-the-clock opioid therapy for persistent cancer pain. Opioid tolerant is defined as patients taking at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid daily for 1 week or longer. Patients must remain on around-the-clock opioids when taking fentanyl citrate transmucosal lozenges. For renewal: assessment of pain severity and functional ability, progress towards achieving therapeutic goals, presence of adverse effects, plan of care including duration of treatment. Chart notes that assess the patient for possible aberrant drug-related behaviors, substance use, and psychological issues. Patients remain on around-the-clock opioids when taking fentanyl citrate transmucosal lozenges.

AGE RESTRICTION

16 years of age and older.

PRESCRIBER RESTRICTION

Pain management specialist or oncologist.

COVERAGE DURATION

6 months.

OTHER CRITERIA

N/A

ADCIRCA (TADALAFIL)

MEDICATION(S)

ADCIRCA

COVERED USES

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

EXCLUSION CRITERIA

Concomitant organic nitrates. Concomitant Guanylate Cyclase (GC) Stimulators.

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC). PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than or equal to 25 mm Hg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mm Hg, and pulmonary vascular resistance (PVR) of greater than 3 Wood units (RHC report must be attached).

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist, Pulmonologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

ADEMPAS (PENDING CMS APPROVAL)

MEDICATION(S)

ADEMPAS

MEDICATION(S)

AIMOVIG AUTOINJECTOR, AIMOVIG AUTOINJECTOR (2 PACK)

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation to confirm the diagnosis of migraines based on criteria from the International Classification of Headache Disorders, 3rd edition (ICHD-3). Documentation to confirm intolerance or inadequate response with at least two (2) medications for migraine prophylaxis from the following classes: beta blockers, antidepressants, anticonvulsants.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a headache specialist or neurologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

ARMODAFINIL

MEDICATION(S)

ARMODAFINIL

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

A confirmed diagnosis of either narcolepsy (with sleep study attached), obstructive sleep apnea (with sleep study attached), or shift work disorder.

AGE RESTRICTION

17 years of age and older.

PRESCRIBER RESTRICTION

Sleep specialist or neurologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

BOTOX

COVERED USES

All FDA-approved indications not otherwise excluded from Part D. Sialorrhea associated with disorders of the nervous system or neurologic dysfunction. Hemifacial spasm. Laryngeal dystonia. Spasticity associated with cerebral palsy.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

FOR ALL REQUESTS: Documentation of diagnosis, proposed injection site(s) and the dose that will be injected into each site. IN ADDITION: FOR INITIAL REQUESTS: (1)For OAB with symptoms of urge urinary incontinence, urgency, and frequency: documentation of inadequate response or intolerance to an anticholinergic medication, dose no more than 100 units/treatment. (2)For urinary incontinence due to detrusor overactivity associated with a neurologic condition: inadequate response or intolerance to an anticholinergic medication, dose no more than 200 units/treatment. (3)For prophylaxis of headaches in adult patients with chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer): documentation of inadequate response or intolerance to at least 2 different classes of prophylactic medications (i.e., beta blockers [such as propranolol, metoprolol], amitriptyline, topiramate, valproic acid or its derivatives, verapamil), dose no more than 155 units/treatment. (4)For severe primary axillary hyperhidrosis: documentation of dose no more than 100 units/treatment. (5)For upper or lower limb spasticity in muscle groups FDA-approved for treatment: documentation of dose no more than 400 units/treatment. (6)For blepharospasm associated with dystonia: dose no more than 200 units/treatment. (7)For strabismus associated with dystonia: dose no more than 25 units per muscle per injection. (8)For sialorrhea associated with disorders of the nervous system or neurologic dysfunction, documentation of diagnosis and inadequate response or intolerance to at least 1 anticholinergic medication (e.g., glycopyrrolate). (9)For cervical dystonia: dose no more than 300 units/treatment. FOR RENEWAL REQUESTS: Dose consistent with total units for diagnosis (per initial request criteria). Documentation supporting the need for repeat treatment(s) occurring no sooner than every 3 months.

AGE RESTRICTION

18 years of age or greater for diagnoses of OAB, urinary incontinence, prophylaxis of headaches in patients with chronic migraine, severe primary axillary hyperhidrosis. 16 years of age or greater for

diagnosis of cervical dystonia. 12 years of age or greater for diagnoses of blepharospasm or strabismus associated with dystonia.

PRESCRIBER RESTRICTION

Urologist: OAB, urinary incontinence. Neurologist: Migraine headaches. Neurologist/Physiatrist: Upper limb spasticity, cervical dystonia. Ophthalmologist: Blepharospasm, strabismus.
Dermatologist/Neurologist/Physiatrist: Severe primary axillary hyperhidrosis.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE

COVERED USES

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

EXCLUSION CRITERIA

Concomitant use with biological Disease Modifying Anti-Rheumatic Drugs (DMARDs).

REQUIRED MEDICAL INFORMATION

For moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy: Documentation of an inadequate response, intolerance, or contraindication to one tumor necrosis factor antagonist (such as Enbrel OR Humira). For active psoriatic arthritis and active ankylosing spondylitis: Documentation of an inadequate response, intolerance, or contraindication to at least one DMARD (such as methotrexate, hydroxychloroquine, sulfasalazine, NSAIDs) AND documentation of an inadequate response, intolerance, or contraindication to one tumor necrosis factor antagonist (such as Enbrel OR Humira). For all indications: Documented evaluation of tuberculosis (TB) and active infection.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with a Rheumatologist or Dermatologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

EMFLAZA

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documented diagnosis of Duchenne Muscular Dystrophy confirmed by genetic testing.

AGE RESTRICTION

5 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

ENBREL, ENBREL MINI, ENBREL SURECLICK

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of the results of PPD test and treatment plan to address latent or active infection. For rheumatoid arthritis (RA) or psoriatic arthritis (PsA): Documentation that patient had a trial of or inadequate response to at least one or more DMARD OR intolerant to DMARDs. For psoriasis (Ps) (with greater than 5% body involvement): Documentation that patient is a candidate for systemic therapy or phototherapy and documentation that patient had a trial of or an inadequate response to methotrexate OR UVB therapy OR Acitretin. For psoriasis (Ps) (with less than 5% of body involvement): Documentation that patient had a trial of or an inadequate response to one topical steroid (high or very high potency) AND calcipotriene. For moderately to severely active polyarticular-course juvenile rheumatoid arthritis (JIA): Documentation that patient had a trial of or an inadequate response to one or more DMARD OR is intolerant to DMARDs. For ankylosing spondylitis (AS): Documentation that patient had a trial of or an inadequate response to at least one DMARD OR is intolerant to DMARDs.

AGE RESTRICTION

2 years of age or greater.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with Rheumatologist or Dermatologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

ENDARI

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of sickle cell disease confirmed by chart notes (must be attached).
Documentation that request is to reduce acute complications of sickle cell disease. Documentation of inadequate response to maximum tolerated dose of hydroxyurea therapy OR documented intolerance or contraindication to hydroxyurea therapy. Request is within the FDA labeled dose.

AGE RESTRICTION

5 years of age and older.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with an appropriate specialist such as a Hematologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

EPCLUSA

COVERED USES

All FDA-approved indications not otherwise excluded from Part D, per current American Association for the Study of Liver Diseases (AASLD) - Infectious Disease Society of America (IDSA) Hepatitis C Virus (HCV) Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C.

EXCLUSION CRITERIA

Patients whose medication profile shows treatment with any contraindicated drug-drug interactions (Risk X). Patients who have renal impairment (calculated glomerular filtration rate less than 30 mL/min). Patients who have end stage renal disease (ESRD). Patients who are treated with other Direct Acting Agent (DAA).

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of chronic Hepatitis C (CHC). Lab results must be attached: Hepatitis C virus (HCV) genotype and subtype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), serum creatinine/calculated glomerular filtration rate, liver biopsy or other indirect markers (such as FibroTest or Fibroscan), HBsAg and anti-HBc. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 weeks to 24 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

OTHER CRITERIA

Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

MEDICATION(S)

ESBRIET

COVERED USES

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

EXCLUSION CRITERIA

Other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity, Hermansky-Pudlak syndrome, familial idiopathic pulmonary fibrosis, and chronic hypersensitivity pneumonitis).

REQUIRED MEDICAL INFORMATION

INITIAL REQUESTS: Documented diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by: usual interstitial pneumonia (UIP) pattern present on high resolution computed tomography (HRCT) in patients without lung biopsy, or the combination of HRCT and biopsy pattern in patients with lung biopsy. Documented forced vital capacity (FVC) greater than or equal to 50%. Documented liver function tests (ALT, AST, and bilirubin) and documentation that liver function tests (ALT, AST, and bilirubin) will be monitored periodically throughout the course of treatment as clinically necessary.

RENEWAL REQUESTS: Documentation of rationale for continued therapy (e.g., stability or improvement in the rate of decline for FVC, IPF symptoms, or other prescriber-assessed benefit of therapy). Documentation that liver function tests (ALT, AST, and bilirubin) will be monitored periodically throughout the course of treatment as clinically necessary.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

An appropriate specialist such as a pulmonologist, or in consultation with an appropriate specialist such as a pulmonologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

EXJADE

MEDICATION(S)

EXJADE

COVERED USES

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

EXCLUSION CRITERIA

Creatinine clearance less than 40 mL/min or serum creatinine more than 2 times the age-appropriate upper normal limit, platelet counts less than 50,000/mL, high-risk myelodysplastic syndromes (MDS), advanced malignancies.

REQUIRED MEDICAL INFORMATION

For the treatment of chronic iron overload caused by blood transfusions: Documentation of serum ferritin levels consistently greater than 300 mcg/L. For chronic iron overload in nontransfusion-dependent thalassemia syndromes: Documentation of liver iron concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) AND documentation of serum ferritin level greater than 300 mcg/L on 2 consecutive measurements 1 month apart.

AGE RESTRICTION

Treatment of chronic iron overload caused by blood transfusions: 2 years of age and older. Chronic iron overload in nontransfusion-dependent thalassemia syndromes: 10 years of age and older.

PRESCRIBER RESTRICTION

Hematologist, Oncologist, Hepatologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

FILGRASTIM AGENTS

MEDICATION(S)

NEUPOGEN, ZARXIO

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation or chart notes supporting medication is being used for all FDA-approved indications not otherwise excluded from Part D. For all diagnosis, chart notes that show that lab work (complete blood count with differential including ANC and platelet count) is being monitored prior to initiation of medication and during therapy based on recommendation for that specific diagnosis.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

6 months.

OTHER CRITERIA

N/A

MEDICATION(S)

FORTEO

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of osteoporosis (primary or hypogonadal in men, glucocorticoid-induced or postmenopausal in women). Baseline labs [DXA scan, serum calcium, phosphorus, creatinine, alkaline phosphatase, albumin, 25-hydroxyvitamin D (25[OH]D)]. Documentation of an inadequate response or inability to tolerate at least one of the following: bisphosphonates, hormone replacement therapy, or selective-estrogen receptor modulators (SERMs).

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with an appropriate specialist such as an endocrinologist.

COVERAGE DURATION

12 months, not to exceed 2 years during a patient's lifetime.

OTHER CRITERIA

N/A

MEDICATION(S)

HARVONI

COVERED USES

All FDA-approved indications not otherwise excluded from Part D, per current American Association for the Study of Liver Diseases (AASLD) - Infectious Disease Society of America (IDSA) Hepatitis C Virus (HCV) Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C.

EXCLUSION CRITERIA

Patients whose medication profile shows treatment with any contraindicated drug-drug interactions (Risk X). Patients who have renal impairment (calculated glomerular filtration rate less than 30mL/min). Patients who have end stage renal disease (ESRD). Patients who are treated with other Direct Acting Agent (DAA).

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of chronic Hepatitis C (CHC). Lab results must be attached: Hepatitis C virus (HCV) genotype and subtype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), serum creatinine/calculated glomerular filtration rate, liver biopsy or other indirect markers (such as FibroTest or Fibroscan), HBsAg and anti-HBc. Patients must have HCV genotype 1a, 1b, 4, 5 or 6. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

AGE RESTRICTION

12 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 to 24 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

OTHER CRITERIA

Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

MEDICATION(S)

HETLIOZ

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of complete blindness. Documentation of diagnosis of Non-24-Hour Sleep Wake Disorder indicated by actigraphy or sleep log or diary. Documentation of baseline nighttime sleep time and daytime naptime per sleep log or diary.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a sleep specialist, psychiatrist or neurologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

For renewal: Documentation of response indicated by improvement in nighttime sleep time or reduction in daytime naptime compared to baseline per sleep log or diary.

HIGH RISK MEDICATION

MEDICATION(S)

DIPYRIDAMOLE 25 MG TABLET, DIPYRIDAMOLE 50 MG TABLET, DIPYRIDAMOLE 75 MG TABLET, DISOPYRAMIDE PHOSPHATE, ERGOLOID MESYLATES 1 MG TAB, GUANFACINE HCL, METHYLDOPA, METHYLDOPA-HYDROCHLOROTHIAZIDE, NIFEDIPINE 10 MG CAPSULE, NIFEDIPINE 20 MG CAPSULE

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients 65 years of age and older: Chart notes that document the patient's diagnosis and indication for use of the High Risk Medication. Chart notes documenting that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Chart notes documenting a detailed explanation of the specific benefit established and how the benefit outweighs the potential risk. Chart notes that document that the patient has been counseled on the potential side effects and risks of the High Risk Medication.

AGE RESTRICTION

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

HIGH RISK MEDICATION - BUTALBITAL COMBINATIONS

MEDICATION(S)

BUTALB-CAFF-ACETAMINOPH-CODEIN, BUTALBITAL COMPOUND-CODEINE, BUTALBITAL-ACETAMINOPHN 50-325, BUTALB-ACETAMIN-CAFF 50-325-40, BUTALBIT-ACETAMINOPHEN-CAFF CP, BUTALBITAL-ASA-CAFFEINE CAP

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients 65 years of age and older: Chart notes that document the patient's diagnosis and indication for use of the High Risk Medication. Chart notes documenting that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Chart notes documenting a detailed explanation of the specific benefit established and how the benefit outweighs the potential risk. Chart notes that document that the patient has been counseled on the potential side effects and risks of the High Risk Medication.

AGE RESTRICTION

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

HIGH RISK MEDICATION - FIRST GENERATION ANTIHISTAMINES

MEDICATION(S)

CARBINOXAMINE 4 MG/5 ML LIQUID, CARBINOXAMINE MALEATE 4 MG TAB, CLEMASTINE FUM 2.68 MG TAB, PROMETHAZINE 12.5 MG TABLET, PROMETHAZINE 25 MG TABLET, PROMETHAZINE 50 MG TABLET, PROMETHAZINE 6.25 MG/5 ML SOLN, PROMETHAZINE 6.25 MG/5 ML SYRP, PROMETHAZINE VC, PROMETHAZINE-PHENYLEPHRINE

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients 65 years of age and older: Chart notes that document the patient's diagnosis and indication for use of the High Risk Medication. Chart notes documenting that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Chart notes documenting a detailed explanation of the specific benefit established and how the benefit outweighs the potential risk. Chart notes that document that the patient has been counseled on the potential side effects and risks of the High Risk Medication. For allergic conditions, chart notes documenting an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as levocetirizine, desloratadine, azelastine nasal spray, fluticasone propionate nasal spray, or mometasone nasal spray.

AGE RESTRICTION

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

HIGH RISK MEDICATION - NON-BENZODIAZEPINE SEDATIVE HYPNOTICS

MEDICATION(S)

ESZOPICLONE, ZALEPLON, ZOLPIDEM TARTRATE 10 MG TABLET, ZOLPIDEM TARTRATE ER

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients 65 years of age and older: Chart notes that document the patient's diagnosis and indication for use of the High Risk Medication. Chart notes documenting that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Chart notes documenting a detailed explanation of the specific benefit established and how the benefit outweighs the potential risk. Chart notes that document that the patient has been counseled on the potential side effects and risks of the High Risk Medication. Chart notes documenting an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as temazepam, Rozerem, or Silenor.

AGE RESTRICTION

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

HIGH RISK MEDICATION - NON-COX-SELECTIVE NSAIDS

MEDICATION(S)

INDOMETHACIN 25 MG CAPSULE, INDOMETHACIN 50 MG CAPSULE, INDOMETHACIN ER

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients 65 years of age and older: Chart notes that document the patient's diagnosis and indication for use of the High Risk Medication. Chart notes documenting that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Chart notes documenting a detailed explanation of the specific benefit established and how the benefit outweighs the potential risk. Chart notes that document that the patient has been counseled on the potential side effects and risks of the High Risk Medication. Chart notes documenting an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as ibuprofen, naproxen, nabumetone, etodolac, diclofenac, meloxicam, or topical diclofenac 1% gel.

AGE RESTRICTION

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

HIGH RISK MEDICATION - SKELETAL MUSCLE RELAXANTS

MEDICATION(S)

CARISOPRODOL 250 MG TABLET, CARISOPRODOL 350 MG TABLET, CHLORZOXAZONE 500 MG TABLET, CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, METAXALONE 800 MG TABLET, METHOCARBAMOL 500 MG TABLET, METHOCARBAMOL 750 MG TABLET, ORPHENADRINE ER 100 MG TABLET

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For patients 65 years of age and older: Chart notes that document the patient's diagnosis and indication for use of the High Risk Medication. Chart notes documenting that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Chart notes documenting a detailed explanation of the specific benefit established and how the benefit outweighs the potential risk. Chart notes that document that the patient has been counseled on the potential side effects and risks of the High Risk Medication.

AGE RESTRICTION

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

H.P. ACTHAR

COVERED USES

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

EXCLUSION CRITERIA

Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, sensitivity to proteins of porcine origin, congenital infections suspected in children under 2 years old, or administration of a live or live attenuated vaccine in a patient receiving immunosuppressive doses of H.P. Acthar Gel.

REQUIRED MEDICAL INFORMATION

Documented diagnosis of a FDA-approved indication not otherwise excluded from Part D. Cover under Medicare Part B, if the medication will be furnished by the prescriber/office, administered in the prescriber's office or ambulatory setting, and will be billed by the prescriber/office. Cover under Medicare Part D, if the prescriber wants to have the medication provided by a pharmacy.

AGE RESTRICTION

Infantile Spasms: Less than 2 years of age. Multiple Sclerosis: Greater than or equal to 18 years of age. Other FDA-approved indications not otherwise excluded from Part D: Greater than 2 years of age.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

Infantile Spasms: 1 year. Other FDA-approved indications: 1 month.

OTHER CRITERIA

N/A

MEDICATION(S)

HUMIRA, HUMIRA PEDIATRIC CROHN'S, HUMIRA PEN, HUMIRA PEN CROHN-UC-HS STARTER, HUMIRA PEN PSORIASIS-UVEITIS

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of PPD test results and treatment plan for active or latent infection. For rheumatoid arthritis or psoriatic arthritis: Documentation of an inadequate response to at least 1 DMARD OR an intolerance to DMARDs (e.g. methotrexate, hydroxychloroquine, sulfasalazine). For juvenile idiopathic arthritis: Documentation of an inadequate response to 1 or more DMARD or an intolerance to DMARDs (e.g. NSAIDs, sulfasalazine, methotrexate, azathioprine, cyclosporine, prednisone). For ankylosing spondylitis: Documentation of an inadequate response to 1 or more DMARD or an intolerance to DMARDs (e.g. azathioprine, hydroxychloroquine, D-penicillamine, sulfasalazine, methotrexate and NSAIDs). For chronic to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. For psoriasis (greater than 10% BSA): Documentation of inadequate response to methotrexate or UVB therapy (alone or in combination with other medications) or Acitretin. For psoriasis (less than 10% BSA): Documentation of an inadequate response to 1 topical steroid (high to very high potency) AND calcipotriene 0.005% cream. For active Crohn's Disease, Pediatric Crohn's Disease or active Ulcerative Colitis: Documentation of an inadequate response or intolerance to corticosteroids and methotrexate (for Crohn's disease) or azathioprine, or lost response to or been intolerant to infliximab. For hidradenitis suppurativa/acne inversa: Documentation of an inadequate response or intolerance to 2 of the following: topical antibiotics (e.g. clindamycin), oral antibiotics (e.g. doxycycline, minocycline, amoxicillin-clavulanic acid, clindamycin, rifampin, dapsone), intralesional triamcinolone injections. For uveitis: Documentation of an inadequate response or intolerance to 1 or more oral or topical glucocorticoid (e.g. prednisone, methylprednisolone, prednisolone), immunosuppressant agent (e.g. azathioprine, methotrexate, cyclosporine) or periocular or intraocular injection (e.g. triamcinolone).

AGE RESTRICTION

JIA: 2 years or greater, pediatric CD: 6 years or greater.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with Rheumatologist, Dermatologist, Gastroenterologist or Ophthalmologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

INGREZZA

COVERED USES

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

EXCLUSION CRITERIA

Congenital long QT syndrome, Arrhythmias associated with prolonged QT interval, Severe renal impairment, Pregnancy. Concurrent use of MAO inhibitors or strong CYP3A4 inducers. Documentation that use in other movement disorders (such as Parkinson's disease, Huntington's chorea) have been excluded.

REQUIRED MEDICAL INFORMATION

Documented diagnosis of tardive dyskinesia including copy of Abnormal Involuntary Movement Scale (AIMS) assessment. Documentation of current or former chronic use of a dopamine antagonist (e.g., antipsychotic [first or second generation], metoclopramide, prochlorperazine, droperidol, promethazine, etc) with documentation attached.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Neurologist or psychiatrist as prescribing physician or in consultation.

COVERAGE DURATION

12 months.

OTHER CRITERIA

For renewal: Improvement in symptoms of tardive dyskinesia with both medical records and an updated AIMS assessment attached.

INTRAVENOUS IMMUNE GLOBULIN (IVIG)

MEDICATION(S)

BIVIGAM, CARIMUNE NF 6 GM VIAL, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAPLEX, GAMUNEX-C 1 GRAM/10 ML VIAL, PRIVIGEN

COVERED USES

All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Greater than 2 years old for Chronic Immune Thrombocytopenia.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with an Allergist, Immunologist, Hematologist, or Neurologist.

COVERAGE DURATION

3 months.

OTHER CRITERIA

Subject to Part B vs D review. Documentation showing confirmation of one of the following is present (1) autoimmune mucocutaneous blistering disease pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatrical) pemphigoid, benign mucous membrane pemphigoid, epidermolysis bullosa acquisita and one of the following: (a) inadequate response or inability to tolerate conventional therapy (ie steroids, immunosuppressants) OR (b) rapidly progressive disease in conjunction with conventional therapy (such as steroids, immunosuppressants) (2) erythema multiforme major (SJS, TEN) and SCORTEN level 3 or greater (3) scleromyxedema (4) acute idiopathic thrombocytopenia purpura (ITP) and ONE of the following (a) management of acute bleeding (b) used to increase platelet count prior to surgical procedures (c) severe thrombocytopenia (platelets less than 20,000 per uL) OR (d) high risk for intracerebral hemorrhage (5) chronic ITP and ALL of the following (a) inadequate response or inability to tolerate corticosteroids (b) duration of illness greater than 6 months (c) platelets persistently less than 20,000 per uL (6) chronic B-cell lymphocytic leukemia

with IgG less than 600 mg/dL and recurrent, serious bacterial infections requiring antibiotic therapy (7) hematopoietic stem cell transplant and IgG less than 400 mg/dL (8) HIV and all of the following (a) less than 14 years of age (b) evidence of qualitative or quantitative humoral immunologic defects and (c) current bacterial infection despite antimicrobial prophylaxis (9) solid organ transplant (10) chronic inflammatory demyelinating polyneuropathy confirmed by electrodiagnostic testing or nerve biopsy and an inadequate response or inability to tolerate corticosteroids (11) dermatomyositis or polymyositis diagnosed by laboratory testing (antinuclear or myositis specific antibodies, biopsy, EMG, or MRI) and inadequate response or inability to tolerate steroids or immunosuppressants (12) Guillain Barre syndrome with impaired function (ie unable to stand or walk without aid) (13) Lambert Eaton myasthenic syndrome refractory to steroids, immunosuppressants, or cholinesterase inhibitors (14) multifocal motor neuropathy diagnosed by electrodiagnostic studies (15) acute exacerbations of multiple sclerosis unresponsive to steroids (16) myasthenia gravis refractory to at least 8 weeks of standard therapy (steroids, immunosuppressants, cholinesterase inhibitors) (17) myasthenic crisis (18) stiff person syndrome refractory to standard therapy (muscle relaxants, benzodiazepines, gabapentin) (19) severe, active SLE unresponsive to steroids (20) Kawasaki disease. CONTINUATION OF THERAPY CRITERIA: Documentation of clinical improvement using objective monitoring as appropriate to the diagnosis such as, but not limited to, Rankin score and Activities of Daily Living (ADL) scores.

MEDICATION(S)

JUXTAPID

COVERED USES

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

EXCLUSION CRITERIA

Pregnancy, hepatic impairment (Child-Pugh category B or C) and patients with active liver disease, use of Juxtapid in combination with moderate or strong CYP3A4 inhibitors and/or Kynamro. Prescribers who are not enrolled in the Juxtapid REMS program.

REQUIRED MEDICAL INFORMATION

Chart notes that document a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) with genetic testing attached or post-treatment (if ongoing on therapy), liver function test and lipid profile. Documentation of inadequate response, intolerance or contraindication to standard lipid-lowering regimen containing high potency statins. Documentation of inadequate response or medical reason for not utilizing a PCSK9 inhibitor (Repatha) to manage condition. Documentation that Juxtapid therapy will be used in combination with other lipid-lowering treatments such as statins, fenofibrates, ezetimibe, or niacin.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist or Endocrinologist as prescribing physician or in consultation.

COVERAGE DURATION

6 months.

OTHER CRITERIA

N/A

MEDICATION(S)

KALYDECO

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Chart notes that show that the diagnosis of cystic fibrosis is confirmed. Chart notes that show that appropriate genetic testing has been conducted (confirmation of one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data). Chart notes showing that lab work (baseline liver function, including alanine aminotransferase and asparatate aminotransferase) has been assessed prior to initiation of treatment.

AGE RESTRICTION

For oral granules: 2 years of age and older. For oral tablets: 6 years of age and older.

PRESCRIBER RESTRICTION

Pulmonologist, Endocrinologist, Pediatrician.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

KYNAMRO

COVERED USES

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

EXCLUSION CRITERIA

Hepatic impairment (Child-Pugh Category B or C) and patients with active liver disease, use of Kynamro in combination with a Microsomal Triglyceride Transfer Protein (MTP) inhibitor. Prescribers who are not enrolled in the Kynamro REMS program.

REQUIRED MEDICAL INFORMATION

Chart notes that document a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) with genetic testing attached or post-treatment (if ongoing on therapy) liver function test and lipid profile. Documentation of intolerance or contraindication to standard lipid-lowering regimen containing high potency statins. Documentation of inadequate response or medical reason for not utilizing a PCSK9 inhibitor (Repatha) to manage condition. Documentation that Kynamro therapy will be used in combination with other lipid-lowering treatments such as statins, fenofibrates, ezetimibe, or niacin.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist or Endocrinologist as prescribing physician or in consultation.

COVERAGE DURATION

6 months.

OTHER CRITERIA

N/A

MEDICATION(S)

LETAIRIS

COVERED USES

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

EXCLUSION CRITERIA

Pregnancy. Idiopathic Pulmonary Fibrosis.

REQUIRED MEDICAL INFORMATION

If female of child bearing age, documentation that she will use reliable forms of contraception and that she will have monthly pregnancy tests performed during therapy. Documentation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC), PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than or equal to 25 mm Hg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mm Hg, and pulmonary vascular resistance (PVR) of greater than 3 Wood units (RHC report must be attached). Documentation showing that hemoglobin and hematocrit are being monitored (baseline, at 1 month, and periodically thereafter).

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist, Pulmonologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

LIDOCAINE PATCHES

MEDICATION(S)

LIDOCAINE 5% PATCH

COVERED USES

All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA

Patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

REQUIRED MEDICAL INFORMATION

Documentation to confirm the diagnosis of pain associated with post-herpetic neuralgia or diabetic peripheral neuropathy.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

LINEZOLID

MEDICATION(S)

LINEZOLID, LINEZOLID-D5W

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Vancomycin-resistant *Enterococcus faecium* infection, with or without concurrent bacteremia: chart notes documenting culture results. For nosocomial pneumonia caused by *Staphylococcus aureus* methicillin-susceptible and -resistant strains (MSSA and MRSA) or *Streptococcus pneumoniae* and community-acquired pneumonia caused by *Streptococcus pneumoniae*, including cases with concurrent bacteremia, or MSSA: chart notes that show an inadequate response or inability to tolerate vancomycin IV and clindamycin PO/IV. For uncomplicated skin and skin structure infection caused by MSSA or *Streptococcus pyogenes*: chart notes that show an inadequate response or inability to tolerate at least two (2) of the following: clindamycin PO, trimethoprim-sulfamethoxazole PO, and doxycycline PO or minocycline PO. For complicated skin and skin structure infection, including diabetic foot infections, without concomitant osteomyelitis, caused by MSSA and MRSA, *Streptococcus pyogenes*, or *Streptococcus agalactiae*: chart notes that show an inadequate response or inability to tolerate vancomycin IV and clindamycin PO/IV. For MRSA osteomyelitis or septic arthritis: chart notes that show an inadequate response or inability to tolerate at least two (2) of the following: vancomycin IV, clindamycin PO/IV, and trimethoprim-sulfamethoxazole plus rifampin PO/IV. For all diagnoses: Chart notes showing that lab work (sensitivities, culture results) are being monitored and an Infectious Disease consult.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

10 days to 8 weeks.

OTHER CRITERIA

N/A

MEDICATION(S)

LUCEMYRA

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Diagnosis of acute opioid withdrawal documented by an opioid withdrawal scale (such as Objective Opioid Withdrawal Scale [OOWS], Clinical Opioid Withdrawal Scale [COWS], Subjective Opioid Withdrawal Scale [SOWS]). Documentation of an inadequate response, inability to tolerate, or contraindication to clonidine.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

14 days.

OTHER CRITERIA

N/A

LYRICA (PENDING CMS APPROVAL)

MEDICATION(S)

LYRICA

MEDICATION(S)

LYRICA CR

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation to confirm the diagnosis of pain associated with post-herpetic neuralgia (PHN) or diabetic peripheral neuropathy (DPN). Documentation of an inadequate response or inability to tolerate gabapentin and immediate release Lyrica. Dosage prescribed within package insert requirements (maximum of 330 mg per day for DPN, maximum of 660 mg per day for PHN).

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

MYALEPT

COVERED USES

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

EXCLUSION CRITERIA

Patients with general obesity not associated with congenital leptin deficiency. Patients with HIV-related lipodystrophy. Patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy.

REQUIRED MEDICAL INFORMATION

Documentation showing confirmation of a diagnosis of congenital or acquired generalized lipodystrophy, documentation of prescriber enrollment in Myalept REMS program, and chart notes documenting baseline hemoglobin A1C, glucose, and triglycerides. For members who have been previously approved, chart notes documenting updated hemoglobin A1C, glucose, and triglycerides.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with an endocrinologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

NEULASTA (PENDING CMS APPROVAL)

MEDICATION(S)

NEULASTA

NORDITROPIN

MEDICATION(S)

NORDITROPIN FLEXPRO

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

INITIAL REQUESTS. For children: (1) Growth failure due to growth hormone deficiency (GHD) with confirmation based on (a) clinical assessment of appropriate auxological findings (such as bone age, chronological age, growth chart, height, height velocity), (b) subnormal serum insulin-like growth factor (like IGF-1 or IGFBP), and (c) subnormal response to provocative growth hormone testing. (2) Short stature associated with Noonan Syndrome, Prader-Willi Syndrome, or Turner Syndrome with confirmation based on appropriate genetic testing and assessment of characteristic clinical features. (3) For short stature born small for gestational age with no catch-up growth by age 2-4 years, chart notes confirming diagnosis. (4) Idiopathic Short Stature (ISS) with (a) documentation of a height standard deviation score (SDS) less than -2.25 and associated with growth rates unlikely to allow one to reach normal adult height and (b) documentation of growth chart, growth potential, impaired height velocity for age group, and bone age. For adults: (5) Growth Hormone Deficiency in adults (a) as a result of childhood onset of GHD due to organic disease (attach documentation), (b) adult onset as a result of pituitary or hypothalamic disease, panhypopituitarism, hypothalamic/pituitary surgery, radiation therapy, or trauma, (c) confirmation of adult GHD via subnormal serum insulin-like growth factor-1 (IGF-1), and (d) If IGF-1 is questionable or uncertain, documentation of a subnormal provocative growth hormone testing to confirm adult GHD. RENEWAL REQUESTS: chart notes (for children include documentation of growth chart, height, height velocity, chronological age, bone age, and linear growth potential remaining with open epiphyses) documenting that the patient has tolerated the medication and has an normal IGF-1 level or will have their growth hormone dose adjusted to attain a normal IGF-1 concentration.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Endocrinologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

NUEDEXTA

COVERED USES

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

EXCLUSION CRITERIA

Concomitant use with quinidine, quinine, or mefloquine, Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions. Patients with known hypersensitivity to dextromethorphan. Use with an MAOI or within 14 days of stopping an MAOI. Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide).

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of pseudobulbar affect. For patients at risk of QT prolongation and torsades de pointes, baseline EKG and an EKG evaluation 3-4 hours after the first dose.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with an appropriate specialist such as a neurologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

OCALIVA

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Chart notes that document the patient's diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following: a positive antimitochondrial antibody test, elevated serum alkaline phosphatase level, liver biopsy, or ultrasound scan of the liver. Confirmation that the patient was taking UDCA for at least one year without response and will continue treatment with UDCA while on Ocaliva, or is unable to tolerate UDCA. Labs documenting liver function (AST/ALT, alkaline phosphatase, total bilirubin) and lipid panel. Upon renewal, updated labs documenting liver function and lipid panel.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Hepatologist or Gastroenterologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

OFEV

COVERED USES

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

EXCLUSION CRITERIA

Concomitant use with pirfenidone.

REQUIRED MEDICAL INFORMATION

Documentation showing a diagnosis of idiopathic pulmonary fibrosis.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

OPSUMIT

COVERED USES

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

EXCLUSION CRITERIA

Pregnancy.

REQUIRED MEDICAL INFORMATION

If a woman of childbearing potential, documentation that she will use reliable forms of contraception and that she will have pregnancy tests performed prior to initiation of therapy, monthly during therapy and 1 month after stopping treatment. Documentation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1 with New York Heart Association (NYHA) Functional Class II or III symptoms. Diagnosis confirmed by a complete right heart catheterization (RHC), PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than or equal to 25 mm Hg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mm Hg, and pulmonary vascular resistance (PVR) of greater than 3 Wood units (RHC report must be attached). Documentation should be submitted showing that liver enzymes, hemoglobin and hematocrit were measured at baseline prior to initiation, after the first month and repeated as clinically necessary.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist, Pulmonologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

ORENCIA

MEDICATION(S)

ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT

COVERED USES

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

EXCLUSION CRITERIA

Concomitant use with tumor necrosis factor antagonists and/or other biological rheumatoid arthritis (RA) therapy such as Kineret (anakinra).

REQUIRED MEDICAL INFORMATION

Documented diagnosis of Adult Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, or Adult Psoriatic Arthritis. Documented evaluation of Tuberculosis (TB). Documentation of inadequate response or inability to tolerate one tumor necrosis factor antagonist (such as Enbrel or Humira).

AGE RESTRICTION

2 years of age and older.

PRESCRIBER RESTRICTION

An appropriate specialist such as a rheumatologist, or in consultation with an appropriate specialist such as a rheumatologist

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

ORKAMBI (PENDING CMS APPROVAL)

MEDICATION(S)

ORKAMBI 100 MG-125 MG TABLET, ORKAMBI 200 MG-125 MG TABLET

OXYCONTIN (OXYCODONE ER)

MEDICATION(S)

OXYCODONE HCL ER, OXYCONTIN

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Quantity less than or equal to 2 tablets per day. For all diagnoses, chart notes that document that the patient has an intolerance or failure with sustained release morphine sulfate and fentanyl patches.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Pain management specialist or HIV specialist: chronic pain due to HIV-related neuropathy. Pain management specialist or oncologist: chronic pain due to cancer.

COVERAGE DURATION

6 months.

OTHER CRITERIA

N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 20 MG/4 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMBISOME, AMINOSYN II 10% IV SOLUTION, AMINOSYN II 15% IV SOLUTION, AMINOSYN II 8.5% IV SOLUTION, AMINOSYN II WITH ELECTROLYTES, AMINOSYN 8.5%-ELECTROLYTES SOL, AMPHOTERICIN B 50 MG VIAL, APREPITANT, ASTAGRAF XL, AZASAN, AZATHIOPRINE 50 MG TABLET, BCG VACCINE (TICE STRAIN), BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CLINIMIX, CLINIMIX E 4.25%-5% SOLUTION, CLINIMIX E 5%-20% SOLUTION, CROMOLYN 20 MG/2 ML NEB SOLN, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, DRONABINOL, ELIGARD, EMEND 125 MG POWDER PACKET, ENGERIX-B 20 MCG/ML SYRN, ENGERIX-B PEDI 10 MCG/0.5 SYRN, ENVARSUS XR, FIRMAGON, GRANISETRON HCL 1 MG TABLET, INFLECTRA, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, LEUPROLIDE 1 MG/0.2 ML VIAL, LEUPROLIDE 2WK 1 MG/0.2 ML KIT, LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE 2WK 14 MG/2.8 ML VL, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, LUPRON DEPOT, LUPRON DEPOT (LUPANETA), LUPRON DEPOT-PED 11.25 MG 3MO, LUPRON DEPOT-PED 7.5 MG KIT, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NEBUPENT, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 24 MG TABLET, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT, POTASSIUM CL 10 MEQ/5 ML CONC, POTASSIUM CL 2 MEQ/ML VIAL, POTASSIUM CL 20 MEQ/10 ML CONC, POTASSIUM CL 40 MEQ/20 ML CONC, POTASSIUM CHLORIDE PROAMP, PULMOZYME, RAPAMUNE 1 MG/ML ORAL SOLN, RECOMBIVAX HB 10 MCG/ML SYR, RECOMBIVAX HB 10 MCG/ML VIAL, RECOMBIVAX HB 40 MCG/ML VIAL, RECOMBIVAX HB 5 MCG/0.5 ML SYR, REMICADE, REMODULIN, RENFLEXIS, SANDIMMUNE 100 MG/ML SOLN, SENSIPAR, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 2 MG TABLET, SYNRIPO, TACROLIMUS 0.5 MG CAPSULE, TACROLIMUS 1 MG CAPSULE, TACROLIMUS 5 MG CAPSULE, TOBRAMYCIN 300 MG/5 ML AMPULE, TPN ELECTROLYTES, TPN ELECTROLYTES II, TRAVASOL, TRELSTAR, TRIMETHOBENZAMIDE 300 MG CAP, TROPHAMINE, ZORTRESS

DETAILS

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

MEDICATION(S)

PRALUENT PEN

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Heterozygous Familial Hypercholesterolemia (HeFH): Documentation of either genetic confirmation OR WHO/Dutch Lipid Network Criteria score greater than 6. For patients with clinical atherosclerotic cardiovascular disease (ASCVD): Documentation of diagnosis. For both HeFH and clinical ASCVD: Documentation of prior treatment with at least one high intensity statin therapy (such as atorvastatin 40 mg or 80 mg or rosuvastatin 20 or 40 mg) for at least 3 continuous months with failure to reach target LDL-C (70 mg/dL for ASCVD, 100 mg/dL for HeFH). Documentation discussing statin intolerance, adverse reaction (rhabdomyolysis, muscle pain, muscle weakness associated with statin use) or contraindication (active liver disease, persistent elevation of serum transaminases) if statin therapy cannot be used. Either baseline or post-treatment labs (lipid profile) required for all indications.

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist, Endocrinologist or Lipidologist as prescribing physician or in consultation.

COVERAGE DURATION

6 month initial therapy, 12 month ongoing therapy.

OTHER CRITERIA

N/A

MEDICATION(S)

PROCRIT

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation or chart notes supporting medication is being used for all FDA-approved indications not otherwise excluded from Part D. For all diagnosis chart notes that show that lab work (hemoglobin and iron stores) will be monitored periodically is required. Medication may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

6 months.

OTHER CRITERIA

N/A

MEDICATION(S)

PROMACTA

COVERED USES

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

EXCLUSION CRITERIA

For Chronic hepatitis C infection: Patients who are being treated with direct-acting antiviral agents without interferon.

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis: 1) chronic immune (idiopathic) thrombocytopenia (ITP), 2) thrombocytopenia in patients with chronic hepatitis C, or 3) severe aplastic anemia. For ITP: Documentation of an insufficient response to or intolerance to glucocorticoids (prednisone, high-doses dexamethasone or methylprednisolone), immunoglobulins, or splenectomy. For chronic hepatitis C: Documentation of patient's degree of thrombocytopenia that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For severe aplastic anemia: Documentation of an insufficient response to immunosuppressive therapy.

AGE RESTRICTION

For ITP: 1 year or older. For chronic hepatitis C or severe aplastic anemia: 18 years or older.

PRESCRIBER RESTRICTION

For Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia (ITP) and for patients with severe aplastic anemia: Hematologist. For Thrombocytopenia in patients with chronic hepatitis C: Hematologist or Hepatologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

MEDICATION(S)

RAVICTI

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis by enzymatic, biochemical, or genetic testing and labs including electrolytes, pre-albumin and albumin measurement, (fasting) plasma ammonia concentration and amino acids. Documentation of trial, contraindication, or inadequate response to sodium phenylbutyrate.

AGE RESTRICTION

2 months of age and older.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with an appropriate specialist such as a metabolic or medical genetic specialist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

REPATHA

MEDICATION(S)

REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

COVERED USES

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

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

For Homozygous Familial Hypercholesterolemia (HoFH): Genetic confirmation of 2 mutant alleles in the LDL receptor, Apo B-100 PCSK9 gene OR untreated LDL-C greater than 500 mg/dL OR treated LDL-C greater than or equal to 300 mg/dL with cutaneous or tendonous xanthoma before the age of 10 OR untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia (HeFH) in both parents with documentation attached. Dosing as 420 mg once a month. For HeFH: Documentation of either genetic confirmation OR WHO/Dutch Lipid Network Criteria score greater than 6 with documentation attached. For patients with clinical atherosclerotic cardiovascular disease (ASCVD) or primary hyperlipidemia: Documentation of diagnosis. For both primary hyperlipidemia (including HeFH) and clinical ASCVD: Documentation of prior treatment of at least one high intensity statin therapy (such as atorvastatin 40 mg or 80 mg or rosuvastatin 20 mg or 40 mg) for at least 3 continuous months with failure to reach target LDL-C levels. Documentation discussing statin intolerance, adverse reaction (rhabdomyolysis, muscle pain, muscle weakness associated with statin use) or contraindication (active liver disease, persistent elevation of serum transaminases) if statin therapy cannot be used. Either baseline or post-treatment labs (lipid profile) required for all indications.

AGE RESTRICTION

13 years or older for HoFH, 18 years or older for HeFH and ASCVD.

PRESCRIBER RESTRICTION

Cardiologist, Endocrinologist, or Lipidologist as prescribing physician or in consultation.

COVERAGE DURATION

6 month initial therapy, 12 month ongoing therapy.

OTHER CRITERIA

N/A

REVATIO (SILDENAFIL)

MEDICATION(S)

REVATIO 10 MG/ML ORAL SUSP, SILDENAFIL

COVERED USES

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

EXCLUSION CRITERIA

Concomitant organic nitrates. Concomitant Guanylate Cyclase (GC) Stimulators.

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC), PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than or equal to 25 mmHg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg, and pulmonary vascular resistance (PVR) of greater than 3 Wood units (RHC report must be attached).

AGE RESTRICTION

18 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist, Pulmonologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

THALOMID (PENDING CMS APPROVAL)

MEDICATION(S)

THALOMID

TRACLEER

MEDICATION(S)

TRACLEER

COVERED USES

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

EXCLUSION CRITERIA

Pregnancy. Use with cyclosporine A and/or glyburide.

REQUIRED MEDICAL INFORMATION

If female of child bearing age, documentation that she will use reliable forms of contraception and that she will have monthly pregnancy tests performed during therapy. For pediatric patient aged 3 to 15 years, documentation of diagnosis of idiopathic or congenital pulmonary arterial hypertension (PAH), confirmed by mean pulmonary artery pressure (mPAP) of greater than or equal to 25 mmHg. For patients 15 years or older, documentation of diagnosis of PAH WHO Group 1 with New York Heart Association (NYHA) Functional Class II, III or IV symptoms. Diagnosis confirmed by a complete right heart catheterization (RHC), PAH defined as a resting mPAP of greater than or equal to 25 mmHg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg, and pulmonary vascular resistance (PVR) of greater than 3 Wood units (RHC report must be attached).

Documentation that show that serum transaminases (AST/ALT) and bilirubin are being monitored (prior to initiation of treatment and then monthly).

AGE RESTRICTION

3 years of age and older.

PRESCRIBER RESTRICTION

Cardiologist, Pulmonologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

UPTRAVI (PENDING CMS APPROVAL)

MEDICATION(S)

UPTRAVI

MEDICATION(S)

XIFAXAN

COVERED USES

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

EXCLUSION CRITERIA

Hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any component of the formulation.

REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of Traveler's Diarrhea (TD) caused by noninvasive strains of *Escherichia coli* and trial of or inadequate response to a fluoroquinolone (e.g., ciprofloxacin, levofloxacin) or azithromycin. Dosing as 200 mg tablet 3 times a day. Documentation of diagnosis of Hepatic Encephalopathy (HE) and trial of or inadequate response to lactulose. Dosing as 550 mg tablet 2 times a day. Documentation of Irritable Bowel Syndrome (IBS) with diarrhea and trial of or inadequate response to one antispasmodic agent (e.g., dicyclomine) or one anti-diarrheal agent (e.g., diphenoxylate/atropine, loperamide). Dosing as 550 mg tablet 3 times a day.

AGE RESTRICTION

12 years of age and older for TD. 18 years of age and older for IBS with diarrhea or HE.

PRESCRIBER RESTRICTION

An appropriate specialist or in consultation with a Gastroenterologist, Hepatologist, Infectious Disease specialist.

COVERAGE DURATION

TD: 3 days. HE: 12 months. IBS with diarrhea: 14 days up to 3 treatments.

OTHER CRITERIA

N/A

XOLAIR (PENDING CMS APPROVAL)

MEDICATION(S)

XOLAIR

MEDICATION(S)

XYREM

COVERED USES

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

EXCLUSION CRITERIA

Concomitant use with sedative hypnotics. Succinic semialdehyde dehydrogenase deficiency.

REQUIRED MEDICAL INFORMATION

Documentation showing a diagnosis of excessive daytime sleepiness and cataplexy with narcolepsy.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

Neurologist or sleep specialist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

ZEPATIER (PENDING CMS APPROVAL)

MEDICATION(S)

ZEPATIER