



Medicare Part D Prior Authorization Criteria Employer-based plan Formulary

Prior Authorization Group

ACTHAR

Drug Names

H.P. ACTHAR

Covered Uses

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

Exclusion Criteria

Patients with medical contraindications for use identified in package label, including: scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, presence or history of peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. Treatment of conditions for which Acthar is indicated when they are accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction. For use in children under 2 years of age with congenital infections. Administration of live or live attenuated vaccines in patients receiving immunosuppressive doses of Acthar

Required Medical Information

Acute exacerbation of relapsing-remitting multiple sclerosis (RRMS): Neurology notes including radiologic reports, supporting the diagnosis RRMS must be provided. Documentation of side effects or failure of high-dose oral (prednisone 500mg) and/or IV corticosteroid therapy. Patient is currently being treated with an immunomodulatory drug (i.e. Betaseron, Avonex, Tecfidera, or Copaxone.) Infantile spasms: Documentation supporting diagnosis of infantile spasms, including onset of age, symptom description, EEG results identifying hypsarrhythmia. Dose, frequency, and number of vials per month being requested. Induction of diuresis or proteinuria remission in nephrotic syndrome: Documentation of proteinuria greater than or equal to 3 grams/24 hours. Documentation of side effects or contraindication to corticosteroid therapy OR Documented failure to achieve complete (less than 300 mg/24 hours) or partial remission (300-3500 mg/24 hours) of proteinuria with high dose corticosteroids (prednisone up to 80mg/day). Rheumatic Disorders: Documentation of an acute episode or exacerbation of Psoriatic arthritis, Rheumatoid arthritis or Ankylosing spondylitis. Patient is currently being treated with disease modifying antirheumatic drug (DMARD). Documentation of side effects or failure of high-dose oral and/or IV corticosteroid therapy. Documentation of one of the following diagnoses: systemic lupus erythematosus, systemic dermatomyositis, severe erythema multiforme, Steven-Johnson syndrome, inflammatory ophthalmic disease, symptomatic sarcoidosis. Documentation of prior treatments. Documentation of side effects and/or failure of high-dose oral and/or IV corticosteroid therapy

Age Restrictions

-

Prescriber Restrictions	-
Coverage Duration	3 months
Other Criteria	Infantile Spams: must be less than 2 years of age. For continuation of therapy, documentation must be provided identifying anticipated length of therapy and improvement in clinical signs and symptoms
Prior Authorization Group	ACTIMMUNE
Drug Names	ACTIMMUNE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Supporting documentation including prescription history with intravenous antibiotics, complete blood count (CBC) with differential identifying anemia or thrombocytopenia. Documented diagnosis of Chronic Granulomatous Disease (CGD) and continued frequent serious infectious episodes while receiving prophylactic antibiotics, OR Diagnosis of severe, malignant osteopetrosis supported by radiological reports, documentation of previous therapy with intravenous antibiotics, and other relevant clinical findings that were used to diagnosis osteopetrosis and which will be monitored for outcomes such as: anemia, thrombocytopenia, splenomegaly, optic atrophy, chronic osteomyelitis. Continued therapy will be considered based on demonstrated response identified by reduction in serious infections requiring intravenous antibiotics (CGD), reduction in hospitalizations due to serious infections (CGD), increase in hemoglobin and platelet counts (osteopetrosis), no more than 50dB decrease in hearing and no evidence of progressive optic atrophy (osteopetrosis), no evidence of a serious bacterial infection requiring antibiotics (osteopetrosis).
Age Restrictions	-
Prescriber Restrictions	Hematologist. Oncologist. Endocrinologist. Infectious Disease specialist. Orthopedist. Rheumatologist
Coverage Duration	3 months initial approval. Remainder of calendar year for extension of therapy
Other Criteria	Actimmune is not covered for idiopathic pulmonary fibrosis

Prior Authorization Group	ADAGEN
Drug Names	ADAGEN
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Baseline plasma enzyme adenosine deaminase (ADA) activity confirming diagnosis of ADA deficiency, AND Baseline level of deoxyadenosine triphosphate (dATP) in erythrocytes confirming diagnosis of ADA deficiency, AND Documentation of severe combined immunodeficiency disease, AND Not a suitable candidate for BMT OR failure of BMT. Extension of therapy will be considered if the plasma ADA activity is maintained between 15-35micromol/hr/mL.
Age Restrictions	-
Prescriber Restrictions	Immunologist. Endocrinologist. Geneticist. Metabolic specialist
Coverage Duration	12 months
Other Criteria	-
Prior Authorization Group	ADCIRCA
Drug Names	ADCIRCA, ALYQ, TADALAFIL
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Concomitant use of organic nitrates or guanylate cyclase stimulators. Will not be covered for the treatment of digital ulcers, erectile dysfunction, or in combination therapy with other phosphodiesterase 5 inhibitors. Combination therapy with other PAH agents will not be covered for initial therapy
Required Medical Information	Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying:resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients.(Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of therapy is dependent upon documentation of clinical response and lack of deterioration
Age Restrictions	18 years and older
Prescriber Restrictions	Ordered by or consult with pulmonologist or cardiologist
Coverage Duration	Initial 4 months with 12 month extensions
Other Criteria	-

Prior Authorization Group	ADEMPAS
Drug Names	ADEMPAS
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage will not be provided if any of the following are true: Use in pregnancy, Co-administration of Adempas with a phosphodiesterase inhibitor, including specific PDE-5 inhibitors (i.e. sildenafil, tadalafil, vardenafil), nonspecific PDE inhibitors (i.e. theophylline or dipyridamole), nitrates or nitric oxide donors. Presence of pulmonary veno-occlusive disease
Required Medical Information	If WHO Group I verification of pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying:resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg.. If WHO Group 4, verification of CTEPH diagnosis via ventilation-perfusion scanning and confirmatory pulmonary angiography AND Documentation of persistence/recurrence of CTEPH following surgical treatment OR Documentation that indicates patient is not considered a surgical candidate for the treatment of CTEPH. If WHO Group 1, vasoreactive testing is recommended for all PAH patients (documentation with rationale must be provided for patients for whom this testing is not performed). Documentation of previous and current therapies identifying outcome. Extension of therapy will be dependent upon documentation of clinical response and lack of deterioration
Age Restrictions	18 years old and older
Prescriber Restrictions	Cardiologist or pulmonologist
Coverage Duration	Initial 4 months with 12 month extensions
Other Criteria	For WHO Group 1 (new starts only), documentation is required demonstrating failure or inadequate response to a trial of one of the following: Orally administered PDE-5 inhibitor approved for the treatment of PAH (i.e. tadalafil or sildenafil) or Endothelin receptor antagonist-Letairis, Tracleer, or Opsumit. Combination therapy with other PAH agents will not be covered for initial therapy. Doses greater than the FDA approved maximum dose will not be covered

Prior Authorization Group	ALDURAZYME
Drug Names	ALDURAZYME
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Diagnosis of Hurler or Hurler-Scheie forms of MPS 1 OR diagnosis of Scheie form with moderate to severe symptoms. Baseline forced vital capacity (FVC) less than 80% and ongoing FVC showing improvement with treatment. Distance walked in 6 minutes (6 minute walk test, 6MWT) at baseline and showing improvement with treatment. Documented deficiency in iduronate-2-sulfatase enzyme activity confirming diagnosis of Mucopolysaccharidosis I . Extension of therapy: documentation supports continued benefit based upon improvement in FVC and 6MWT.
Age Restrictions	-
Prescriber Restrictions	-
Coverage Duration	6 months
Other Criteria	Dose and frequency outside of the FDA approved limits will not be covered
Prior Authorization Group	ALPHA1-ANTITRYPSIN REPLACEMENT THERAPY
Drug Names	ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Not covered if any of the following situations are true: 1. PiMZ or PiMS phenotypes 2. Members identified with selective IgA deficiencies (IgA level less than 15mg per dl) who have known antibodies against IgA, since they may experience severe reactions 3. Dosing exceeding package labeling 4.Frequency exceeding once weekly infusions 5. Coverage is not provided for doses exceeding package labeling. 6. Emphysema not due to AAT deficiency.
Required Medical Information	Progressive clinically evident emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV1) post bronchodilation between 30 and 65% predicted except when: 1. Nearly normal pulmonary function if they experience a rapid decline in lung function (FEV1 greater than 120 ml/yr) OR 2. Poor lung function and currently receiving standard treatment. AAT serum level less than 11 micrometer or less than 80mg per dL., rate of decline in forced expiratory volume in 1 second (FEV1) post bronchodilation between 30 and 65% predicted , Phenotype is identified as PiZZ, PiZ(null) or Pi(null)(null) .Continued therapy will be considered based on demonstrated response in slowing progression of lung function decline
Age Restrictions	-
Prescriber Restrictions	Must be ordered or followed by a pulmonologist
Coverage Duration	3 months initial approval. Remainder of contract year for ext of therapy.
Other Criteria	-

Prior Authorization Group	AMPYRA
Drug Names	AMPYRA, DALFAMPRIDINE ER
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Prior history of seizure. Moderate or severe renal impairment defined as a creatinine clearance (CrCl) of less than or equal to 50 mL/min. History of hypersensitivity to Ampyra or 4-aminopyridine. Use with 4-aminopyridine or fampridine
Required Medical Information	Neurology chart notes must be provided including all radiologic reports supporting the dx of MS. Prior to dalfampridine treatment timed 25-foot walk (T25FW) result. (Assistive devices must be consistently used across pre-treatment walk tests and identified in the chart notes.) For continuation of therapy for second request: Current T25FW result be provided showing an improvement over the baseline average. Continuation thereafter: T25FW result identifying a continued improvement over the fastest baseline maximum speed. Individuals must maintain initial improvement over baseline in T25FW at each extension.
Age Restrictions	18 years old and older
Prescriber Restrictions	Restricted to neurologists
Coverage Duration	Initial: 3 months. Continuation 12 months
Other Criteria	Currently receiving a stable dose of disease-modifying therapy for RRMS (or on a stable dose of disease-modifying therapy for all other forms of MS if appropriate) for at least 60 days (e.g. no changes in therapy for 60 days prior to start of dalfampridine treatment). Continued approval of Ampyra will not be allowed if the T25FW declines from baseline. Will not be covered for the prevention of symptoms

Prior Authorization Group	ANTIDEPRESSANTS
Drug Names	FETZIMA, FETZIMA TITRATION PACK, TRINTELLIX
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Use in combination with MAOIs or linezolid.
Required Medical Information	Documentation identifying diagnosis of major depressive disorder. Previous therapies tried
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	12 months.
Other Criteria	Documentation must include failure or inadequate response to a minimum of a 6 week trial of two of the following: Citalopram, Escitalopram, Fluoxetine, Paroxetine, Sertraline, Trazodone, Venlafaxine, Duloxetine

Prior Authorization Group	ANTIMETABOLITES
Drug Names	ALIMTA, LONSURF, VYXEOS, ZALTRAP
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of diagnosis for use, current chart notes and any previous and concurrent therapies
Age Restrictions	-
Prescriber Restrictions	Oncologist
Coverage Duration	12 months
Other Criteria	-
Prior Authorization Group	ARCALYST
Drug Names	ARCALYST
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	The use of Arcalyst will not be considered medically necessary for any of the following: 1. Dosing other than FDA approved dosing regimen. 2. In combination with other interleukin-1 inhibitor. 3. In combination with TNF inhibitor.
Required Medical Information	Genetic test identifying CIAS1 (Cold-Induced Autoinflammatory Syndrome 1) gene mutation (also known as NLRP3, NALP3 or PYPAF). Skin biopsy if performed. Serum amyloid. C-reactive protein. Extension of therapy will be medically necessary if documentation identifies symptom improvement or disease stability.
Age Restrictions	12 years old and older
Prescriber Restrictions	Restricted to Rheumatologist, immunologist or dermatologist
Coverage Duration	Initial 6 month approval followed by an additional 6 months if medically necessary.
Other Criteria	-
Prior Authorization Group	AUBAGIO
Drug Names	AUBAGIO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Severe hepatic impairment
Required Medical Information	Diagnosis of relapsing form of multiple sclerosis, liver function test results, CBC results, patient progress notes.
Age Restrictions	18 years and older
Prescriber Restrictions	Neurologist
Coverage Duration	12 months
Other Criteria	-

Prior Authorization Group	AURYXIA
Drug Names	AURYXIA
Covered Uses	For the control of serum phosphorous levels in hyperphosphatemia adult patients with chronic kidney disease on dialysis
Exclusion Criteria	For the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. Prescription medications used as vitamin or mineral products, are excluded from Medicare Part D coverage. Auryxia is considered a vitamin or mineral product when used for the treatment of iron deficiency anemia. For the treatment of hyperphosphatemia in adult patients with chronic kidney disease NOT on dialysis
Required Medical Information	Documentation of diagnosis, current chart notes
Age Restrictions	-
Prescriber Restrictions	Ordered by or Consult with nephrologist
Coverage Duration	12 months
Other Criteria	-

Prior Authorization Group	B VS. D
Drug Names	ABELCET, ACETYLCYSTEINE, ACYCLOVIR SODIUM, ADRUCIL, ALBUTEROL SULFATE, AMBISOME, AMINOSYN 7%/ELECTROLYTES, AMINOSYN II, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-PF 7%, AMINOSYN-RF, AMPHOTERICIN B, APREPITANT, ASTAGRAF XL, AZASAN, AZATHIOPRINE, BENDEKA, BLEOMYCIN SULFATE, BROVANA, BUDESONIDE, CLADRIBINE, CROMOLYN SODIUM, CYCLOPHOSPHAMIDE, CYCLOSPORINE, CYCLOSPORINE MODIFIED, CYTARABINE AQUEOUS, ENGERIX-B, ENVARUSUS XR, FLUOROURACIL, GANCICLOVIR, GENGRAF, GRANISETRON HCL, HEPATAMINE, INTRALIPID, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE/ALBUT, LEVALBUTEROL, LEVALBUTEROL HCL, LEVALBUTEROL HYDROCHLORID, MYCOPHENOLATE MOFETIL, MYCOPHENOLIC ACID DR, NEBUPENT, NEORAL, NEPHRAMINE, NULOJIX, ONDANSETRON HCL, ONDANSETRON ODT, PERFOROMIST, PREMASOL, PROCALAMINE, PROGRAF, PROSOL, PULMOZYME, RAPAMUNE, RECOMBIVAX HB, SANDIMMUNE, SENSIPAR, SIMULECT, SIROLIMUS, TACROLIMUS, THYMOGLOBULIN, TOBRAMYCIN, TOBRAMYCIN SULFATE, TRAVASOL, TROPHAMINE, VARUBI, VINBLASTINE SULFATE, VINCASAR PFS, VINCRISTINE SULFATE, ZORTRESS
Covered Uses	NA
Exclusion Criteria	-
Required Medical Information	-
Age Restrictions	-
Prescriber Restrictions	-
Coverage Duration	NA
Other Criteria	-

Prior Authorization Group	BENLYSTA
Drug Names	BENLYSTA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Diagnosis of active systemic lupus erythematosus (SLE) with one of the following lab results identifying the patient is auto-antibody positive: Antinuclear antibody(ANA) positive greater than or equal to 1:80 OR Anti-double-stranded DNA greater than or equal to 30IU/mL. Documentation that the patient has at least four of the following conditions: malar rash, arthritis, hematologic disorder, discoid rash, serositis, immunologic disorder, photosensitivity, renal disorder, antinuclear antibodies, oral ulcers or neurologic disorder
Age Restrictions	18 years old and older
Prescriber Restrictions	Rheumatologist
Coverage Duration	6 months initial, extension 12 months
Other Criteria	Must have failure or inadequate response to a 12 week trial of two of the following categories unless contraindicated: corticosteroids, anti-malarials (chloroquine, hydroxychloroquine), or immunosuppressives (methotrexate, azathioprine, cyclophosphamide, mycophenolate)

Prior Authorization Group	BIOLOGIC RESPONSE MODIFIERS
Drug Names	BAVENCIO, DAURISMO, FARYDAK, IBRANCE, IDHIFA, IMFINZI, KISQALI, KISQALI FEMARA 200 DOSE, KISQALI FEMARA 400 DOSE, KISQALI FEMARA 600 DOSE, LIBTAYO, LUMOXITI, LYNPARZA, MYLOTARG, NINLARO, OPDIVO, RUBRACA, TALZENNA, VELCADE, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, YERVOY, ZEJULA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of diagnosis for use, current chart notes and any previous and concurrent therapies
Age Restrictions	-
Prescriber Restrictions	Oncologist
Coverage Duration	12 months
Other Criteria	-

Prior Authorization Group	CAYSTON
Drug Names	CAYSTON
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Known allergy to aztreonam
Required Medical Information	Diagnosis of cystic fibrosis and sputum culture positive for Pseudomonas aeruginosa, FEV1 results
Age Restrictions	7 years old and older
Prescriber Restrictions	Pulmonologist and infectious disease
Coverage Duration	12 months
Other Criteria	Patient must have FEV1 between 25% and 75% of predicted and not be colonized with Burkholderia cepacia

Prior Authorization Group	CESAMET
Drug Names	CESAMET
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Hypersensitivity to any cannabinoid
Required Medical Information	Documentation that the member is receiving chemotherapy for the treatment of cancer and is experiencing nausea and vomiting. Previous antiemetic treatments that member has failed.
Age Restrictions	18 years and older
Prescriber Restrictions	Ordered by or consult with an oncologist
Coverage Duration	12 months
Other Criteria	Member must have failed therapy with the following conventional antiemetic treatments: aprepitant or rolapitant in combination with ondansetron, or dolasetron, or granisetron.

Prior Authorization Group	CIALIS FOR BPH
Drug Names	CIALIS, TADALAFIL
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use of nitrate-based drugs (nitroglycerin) for heart conditions, Hypersensitivity reaction to Cialis or Adcirca
Required Medical Information	Cialis(tadalafil) 2.5mg or 5mg may be considered medically necessary when the following criteria are met. Enlarged prostate AND bothered by symptoms for at least 50 percent of the time over one month. Moderate to severe uncontrolled symptoms due to benign prostatic hyperplasia (BPH) with an American Urological Association Symptom Index (AUA-SI) greater than 8. (Symptoms include incomplete emptying, frequency, intermittency, urgency, weak stream, straining, nocturia.) Failure (defined less than 50 percent improvement of symptoms after 3 month trial), to the following two different combination therapies: alpha-blocker with an anticholinergic and alpha-blocker with a 5-alpha-reductase inhibitor, OR has a contraindication or are intolerant to all appropriate drug classes used to treat BPH. For continued therapy: must be a reduction in symptoms.
Age Restrictions	18 years old and older
Prescriber Restrictions	Restricted to urologists (or urology consult identified)
Coverage Duration	Remainder of the contract year.
Other Criteria	Will not be covered solely for: erectile dysfunction (ED) for standard plans, status post radical prostatectomy, in combination with other PDE 5 inhibitors or solely to reduce PSA level. The use of Cialis 2.5mg tablets will be approved for members with a creatinine clearance of 30 to 50mL/min or in patients that are unable to tolerate the 5mg dose
Prior Authorization Group	CYCLOBENZAPRINE
Drug Names	CYCLOBENZAPRINE HYDROCHLO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of indication of use. The prescriber must be aware that the medication poses a high risk for use in most patients 65 years of age or older. Documentation that the prescriber acknowledges that medication benefit outweigh potential risk in patients 65 years of age or older
Age Restrictions	Prior authorization only applies to patient 65 years or older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	For musculoskeletal pain, the patient must have a documented failure of metaxalone. For fibromyalgia, the patient must have documented failure of two of the following medications: duloxetine, gabapentin or Lyrica.

Prior Authorization Group	CYSTARAN
Drug Names	CYSTARAN
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Diagnosis of cystinosis with corneal crystal accumulation, Corneal cystine crystal score prior to start of therapy
Age Restrictions	-
Prescriber Restrictions	Ophthalmologist
Coverage Duration	12 months
Other Criteria	For continuation of therapy documentation must be provided identifying either a lack of increase or reduction in the corneal cystine crystal score.
Prior Authorization Group	DARAPRIM
Drug Names	DARAPRIM
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Megaloblastic anemia due to folate deficiency
Required Medical Information	Chart notes identifying Daraprim will be used for the prophylaxis or treatment of toxoplasmosis, prophylaxis or treatment of pneumocystis pneumonia (PCP) or prophylaxis or treatment of malaria
Age Restrictions	-
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	For the prophylaxis of Toxoplasmosis, and prophylaxis or treatment of PCP -must have contraindication to the use of trimethoprim-sulfamethoxazole. For the prophylaxis or treatment of malaria must have failed therapy with, or have a contraindication to the use of atovaquone-proguanil and mefloquine
Prior Authorization Group	DIFICID
Drug Names	DIFICID
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Stool sample positive for clostridium difficile toxin.
Age Restrictions	18 years old and older
Prescriber Restrictions	Restricted to Infectious Disease and gastroenterologist.
Coverage Duration	10 days
Other Criteria	Failure of a 10-14 day course of treatment of metronidazole and oral vancomycin. (Recurrence of c. difficile AFTER treatment with vancomycin or metronidazole does not meet the criteria for failure of vancomycin or metronidazole.)

Prior Authorization Group	DRONABINOL
Drug Names	DRONABINOL
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Hypersensitivity to any cannabinoid
Required Medical Information	Documentation of diagnosis, and documentation of any previous therapies
Age Restrictions	For AIDS-associated loss of appetite, 18 years and older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	For chemotherapy induced nausea and vomiting associated with cancer chemotherapy or for postoperative nausea and vomiting: member must have failed therapy with the following conventional antiemetic treatments: aprepitant or rolapitant in combination with ondansetron, or dolasetron, or granisetron. For AIDS-associated loss of appetite the member must have failed therapy with a trial of megestrol.

Prior Authorization Group	ENBREL
Drug Names	ENBREL, ENBREL MINI, ENBREL SURECLICK
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Psoriatic Arthritis: Documentation identifying number of tender and swollen joints, PE findings, diagnosis of psoriasis or family history (diagnosis in a 1st or 2nd degree relative) of psoriasis, previous and current therapies and responses. RA: chart notes identifying persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration. AS: Documented significant clinical symptoms such as those identified in the BASDAI greater than 4 (0-10). Psoriasis: For initial treatment, documentation of moderate to severe plaque psoriasis
Age Restrictions	Polyarticular juvenile idiopathic arthritis-ages 2 and older, plaque psoriasis-ages 4 and older. Over 18 years old for all other indications.
Prescriber Restrictions	Restricted to rheumatologists or immunologists for members with arthropathies, dermatologists
Coverage Duration	12 months
Other Criteria	A. For moderate to severe active adult RA the following must be met: Failed to respond to 1 or more nonbiologic DMARDs, 1 of which is an adequate trial of a maximally tolerated dose of MTX. If the member has a contraindication or significant intolerance to methotrexate, the member must have failed to respond to an adequate trial of 1 other DMARD at a maximally tolerated dose for at least 3 months. B. For moderate to severe JIA as indicated by 4 affected joints with limitation of motion, pain, tenderness or both, or persistent symptoms, the following criteria must be met: Failure to respond to an adequate trial of one DMARD. C. For the treatment of moderate to severe psoriatic arthritis as indicated by 3 or more tender joints AND 3 or more swollen joints on 2 separate occasions at least 1 month apart, the following criteria must be met: Must have had an inadequate response to at least 1 NSAID, and Failed to respond to an adequate trial of at least 1 DMARD. D. Enbrel for plaque psoriasis will be considered medically necessary when ALL of the following criteria are met: Moderate to severe chronic plaque psoriasis or involvement of the palms, soles of feet, facial or genital regions. An appropriate treatment trial of at least one of the following agents was not effective: MTX, oral retinoids, cyclosporine. E: For AS:failure during a 3 month period of 1 NSAID at maximum tolerated dose and BASDAI greater than or equal to 4 and Failure of a 12 week trial of sulfasalazine at maximum tolerated dose in patients with persistent peripheral arthritis, no trial of DMARDS required for pure axial manifestations. Continued coverage for all indications will be based on significant symptom improvement.

Prior Authorization Group	EPIDIOLEX
Drug Names	EPIDIOLEX
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of diagnosis, current chart notes and any previous and concurrent therapies
Age Restrictions	2 years and older
Prescriber Restrictions	Ordered by or Consult with neurologist
Coverage Duration	12 months
Other Criteria	-

Prior Authorization Group	EPOETIN
Drug Names	EPOGEN, PROCRIT
Covered Uses	All medically accepted indications not otherwise excluded from Part D and MDS
Exclusion Criteria	Uncontrolled hypertension
Required Medical Information	Documentation that cause of anemia is due to one of the following: 1)chronic kidney diseases (serum creatinine greater than 3mg/dl, crcl less than 60ml/min, or GFR less than 60ml/min/1.73m2) or on dialysis or 2)Zidovudine in HIV-infected patient receiving less than 4200mg/week of zidovudine with serum epo level less than 500 or 3)Chemotherapy in patients with cancer or 4) Reduction of allogeneic red blood cell transfusions in patients undergoing elective noncardiac, nonvascular surgery or 5)Myelodysplastic syndrome (MDS) with less than 10% blasts and pretreatment serum epo level 500 or less. Documentation that all other conditions that can cause anemia including folate or B12 or iron def, hemolysis, bleeding or bone marrow fibrosis, acute or chronic blood loss have been ruled out. Current Hgb level, ferritin and transferrin saturation level must be submitted with each request/extension. For MDS transfusion records must be submitted with each request
Age Restrictions	restricted to 5 years and older for anemia due to chemo
Prescriber Restrictions	-
Coverage Duration	Initial 3 month approval, extensions up to 6 months. Pre-surgical limited to 1 month.
Other Criteria	For all request and extension-ferritin must be at least 100ng/ml and transferrin sat at least 20%. For all indication except pre surgical adjuvant therapy(PAT): Hgb level must be less than 10g/dL at start of treatment. For PAT Hgb level must be between 10 and 13 g/dL and not be a candidate for autologous blood transfusions. For extension request Hgb level should be less than 11g/dL for all indication except for zidovudine treated patients where Hgb should be less than 12g/dL. For MDS must show a 50% reduction in transfusion reqs OR Hgb has normalized to 10 gm/dL or more. For anemia due to chemotherapy: must have non-myeloid malignancy, must have greater than a 1g/dL increase in Hgb after 8 weeks of treatment and will only be covered for 8 weeks following final dose of chemotherapy.

Prior Authorization Group	ESBRIET
Drug Names	ESBRIET
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documented diagnosis of idiopathic pulmonary fibrosis (IPF), HRCT results identifying the presence of a usual interstitial pneumonia (UIP) pattern, Lung biopsy confirming UIP if available, PE findings and liver function tests.
Age Restrictions	18 years and older
Prescriber Restrictions	Ordered by, or by consult with, a pulmonologist.
Coverage Duration	6 months
Other Criteria	Must have FVC greater than or equal to 50% of predicted and a carbon monoxide diffusing capacity of greater than or equal to 30% of predicted prior to start of therapy. Must rule out other causes of interstitial lung disease such as domestic and occupational environmental exposures, connective tissue disease and /or drug toxicity. LFT's must be less than 5x ULN. For continuation of therapy documentation must identify improvement or maintenance of disease (less than a 10% decline in FVC).
Prior Authorization Group	FABRY DISEASE
Drug Names	FABRAZYME, GALAFOLD
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	The use of Fabrazyme will not be considered medically necessary for members who are carriers of the disease. For Galafold, uncertain clinical significance of variant status should be determined by a genetics professional. Doses or frequency exceeding FDA approved dosing regimen.
Required Medical Information	Treatment with Fabrazyme will be considered medically necessary when the following criteria are met: Diagnosis of Fabry disease confirmed by one of the following: Enzyme assay demonstrating a deficiency of alpha-galactosidase activity OR DNA testing. Treatment with Galafold will be considered medically necessary when the following criteria are met: a. Diagnosis of Fabry disease b. Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. For continued coverage: Documentation of positive clinical response to therapy.
Age Restrictions	-
Prescriber Restrictions	-
Coverage Duration	Remainder of the contract year.
Other Criteria	-

Prior Authorization Group	FENTANYL
Drug Names	FENTANYL CITRATE ORAL TRA, FENTORA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Increased strength and/or frequency other than approved dosing are excluded. Treatment of acute or postoperative pain. Combination use of short-acting fentanyl products. Monotherapy.
Required Medical Information	Diagnosis of cancer. Documentation indicates that use is for breakthrough cancer pain. For extension of therapy, documentation must identify 1. continued benefit from therapy, and 2. dosing of long-acting product has been evaluated and is at the maximum tolerated dose.
Age Restrictions	Transmucosal solid dosage form restricted to 16 and older. All other forms restricted to 18 years and older.
Prescriber Restrictions	Restricted to oncologists and pain management specialists
Coverage Duration	Initial 3 months approval followed by 6 month intervals.
Other Criteria	Fentanyl oral transmucosal or buccal solid dosage forms require prior authorization (for all quantities) and may be considered medically necessary when all of the following criteria are met: 1. Immediate-release (short-acting) opioid drugs are ineffective supported by documentation of excessive rescue doses used. 2. Already receiving but tolerant to a chronic pain around-the-clock extended release formulation. (Opioid tolerant patients are those who are taking around-the-clock medicine consisting of at least 60mg oral morphine, 30mg oral oxycodone, 8mg of oral hydromorphone, or an equianalgesic dose of another opioid daily for one week or longer.)

Prior Authorization Group	FIRAZYR
Drug Names	FIRAZYR
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of the following must be provided: 1. Laboratory data confirming diagnosis of hereditary angioedema (HAE) with on of the following: a.C1-INH and serum complement factor 4 level below the reference range along with a serum C1q level within normal reference range, OR b. C1-INH level that is normal or elevated but dysfunctional, low C4 level and normal C1q level, OR c. Normal C1-INH with normal functional assay and normal C4 and C1q levels AND Family history of HAE, if any. 2. Medications that may trigger or worsen angioedema have been evaluated and discontinued if appropriate. (Examples of these are estrogen contraceptives, hormone replacement therapy, and ACE-Inhibitors.) 3. Prescribed for acute attacks (not for prophylaxis) and not for stock for future attacks (i.e. not stockpiling). 4. Member is not currently receiving medications that may trigger or worsen angioedema. For continued use, the following documentation must be identified following Firazyr use: diminished symptoms, decreased severity of attack, reduced duration of attacks, and decreased hospitalizations when compared to previous therapies. Please provide date of last attack.
Age Restrictions	18 years old and older
Prescriber Restrictions	Allergist, immunologist, or hematologist
Coverage Duration	Three month intervals
Other Criteria	Not to be used in combination with Kalbitor or Berinert. Triggers (e.g. surgery, major dental work, etc.) of attacks have been prophylactically treated appropriately and HAE attacks persist OR contraindication (such as pregnancy or lactatin) or severe intolerance to attenuated androgens (e.g. danazol). Member has been compliant with preventative therapy, therapy has been optimized, and HAE attacks persist.

Prior Authorization Group	FIRDAPSE
Drug Names	FIRDAPSE
Covered Uses	For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.
Exclusion Criteria	Patients with a history of seizures or seizure disorder.
Required Medical Information	1.Diagnosis of LEMS 2. Documentation of a baseline clinical muscle strength assessment (examples may include but are not limited to, a Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW)).
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Initial coverage: 6 months Continued coverage: 12 months
Other Criteria	Continuation of therapy will be based on a documented positive response evidenced by an updated stable or improved clinical muscle strength assessment. Examples may include but are not limited to, a Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW). Non-FDA approved diagnoses will be evaluated according to the CMS medically accepted indications requirements in Chapter 6 of the Medicare Prescription Drug Benefit Manual.

Prior Authorization Group	FORTEO
Drug Names	FORTEO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Forteo required information: Diagnosis of osteoporosis in Postmenopausal female or primary hypogonadal male at high risk of fracture. Glucocorticoid induced osteoporosis on a daily dose equivalent to 5mg or greater of prednisone for at least 3 months and at high risk for fracture. And one of the following: 1. The member has a BMD T-score of less than or equal to 2.5 at the hip, femoral neck or spine and has documented failure of an adequate trial of oral alendronate, or ibandronate unless the member has a contraindication or intolerance to bisphosphonates: or 2. New osteoporotic/fragility fracture despite an adequate trial of oral alendronate or risedronate. For continued therapy must demonstrate maintenance in BMD of the lumbar spine, femoral neck, or whole body
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	24 months
Other Criteria	Doses exceeding the FDA approved package labeling are not covered. Teriparatide is not a covered benefit in the following situations: prevention of osteoporosis in men and women, members with Paget's disease or unexplained elevations of alkaline phosphatase, members with a history of bone metastases, skeletal malignancies and/or metabolic bone disease other than osteoporosis, members with hypercalcemia, or in combination with a bisphosphonate. Teriparatide is not covered after two years of treatment.

Prior Authorization Group	GAUCHERS DISEASE
Drug Names	CEREZYME, MIGLUSTAT, VPRIV, ZAVESCA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	The use of these agents will not be considered medically necessary in the following situations: members with Type 2 or Type 3 Gaucher's Disease. asymptomatic Type 1 disease. carriers of Gaucher's Disease. combination use of any of these agents. Miglustat is not covered for severe disease (severe disease defined as a hemoglobin concentration below 9 g/dL or a platelet count below 50 x 10 to the 9th/L or active bone disease). Miglustat is not covered for diagnosis other than Type 1 Gaucher Disease. Miglustat is not covered if there is no documented allergy, hypersensitivity, or poor venous access to enzyme replacement therapy. These agents are not covered for any diagnosis other than Gaucher's disease.
Required Medical Information	Medical information required for miglustat is as follows: diagnosis of Gaucher's Disease Type 1 confirmed by biochemical assay AND member is experiencing symptomatic manifestations of the disease AND member has a contraindication for use of enzyme replacement therapy such as allergy, hypersensitivity reaction or poor venous access. Miglustat is restricted 18 years and greater.
Age Restrictions	
Prescriber Restrictions	-
Coverage Duration	Remainder of the contract year.
Other Criteria	-

Prior Authorization Group	GRASTEK
Drug Names	GRASTEK
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, unstable or uncontrolled asthma. History of eosinophilic esophagitis. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy
Required Medical Information	Documented allergic rhinitis with or without conjunctivitis. Positive skin test or in vitro testing for pollen-specific IgE antibodies for the specific allergen extract OR a strongly cross-reactive allergen to the following: Pollen-specific IgE antibodies-Timothy Grass. Strongly Cross-Reactive Allergen-members of the pooideae sub family (includes but not limited to orchard, fescue, ryegrass, June, and sweet vernal). Allergen must be identified as the cause of the major clinical symptoms
Age Restrictions	5 through 65 years of age
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	Treatment must be initiated at least 12 weeks before expected pollen season based on geographic location (start of season usually late April in Northeast). Therapy should be initiated in January/February in Northeast. Documentation must identify failure of at least two of the following treatments: Intranasal corticosteroids, Oral antihistamine, or Oral leukotriene receptor antagonist. For continuation of treatment, must have benefits of treatment (decrease of symptoms, increase tolerance to grass pollen) along with medication compliance based on prescription claims review. Extension requests for ongoing therapy after end of allergen season-Prescription claims review must show compliance with each renewal. Patients that were on active therapy daily for 3 consecutive years must wait at least 1 year until coverage may be reinitiated, unless patients experience a documented severe increase in symptoms compared to the past 3 years. Will not be covered if receiving subcutaneous allergen immunotherapy

Prior Authorization Group	GROWTH HORMONE THERAPY
Drug Names	HUMATROPE, HUMATROPE COMBO PACK, NORDITROPIN FLEXPPO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	GH will not be covered for the following: active malignant condition. If GHD results from an intracranial tumor, absence of tumor growth or tumor recurrence for at least 6 months prior to therapy initiation. GH is not indicated for treatment of wounds or burns. PWS with 1 or more risk factors including severe obesity, h/o respiratory impairment or sleep apnea, or unidentified respiratory infection. Catabolic illnesses or to improve muscle strength or exercise tolerability. Members w/ active proliferative or severe non-proliferative (preproliferative) diabetic retinopathy. Current or predicted ht without GH therapy greater than or equal to mid-parental height. Non-euthyroid state. Ext of therapy for children for GHD will not be covered if no further growth or mid-parental ht is achieved OR epiphyseal fusion is complete OR bone age indicates growth is complete OR renal transplant has occurred (for CRI) OR growth rate of 2cm/yr has not occurred. IGF-1 in combo with GH is not covered.
Required Medical Information	A. GHD: ht must be beneath 3rd percentile of normal or 2 SD below 50th percentile AND growth velocity must be less than 10th percentile of normal or greater than 2 SD below the mean AND lack of response to 2 separate GH provocative tests. B. Children with Turners Syndrome: present ht must be below the 5th percentile of normal OR ht greater than 2 SD below the mid-parental ht prediction or growth velocity less than 25% for bone age and bone age less than 14 years. C. Children w/ PWS: Severe hypotonia in neonates, followed by hyperphagia and obesity. D. ISS: in the presence of GH deficiency AND with open growth plates AND ht less than the 3rd percentile AND growth velocity less than 10th percentile.
Age Restrictions	Per package label
Prescriber Restrictions	Endocrinologists or Nephrologists
Coverage Duration	12 months
Other Criteria	-
Prior Authorization Group	HEPATITIS C TREATMENT
Drug Names	DAKLINZA, EPCLUSA, HARVONI, MAVYRET, SOVALDI, VOSEVI, ZEPATIER
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of chronic hepatitis C infection, HCV RNA level and genotype, Child-Pugh class
Age Restrictions	-
Prescriber Restrictions	Infectious disease physician, Gastroenterologist or Hepatologist
Coverage Duration	12 to 24 weeks based on drug and indication
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance

Prior Authorization Group	HEREDITARY ANGIOEDEMA
Drug Names	CINRYZE, RUCONEST
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Diagnosis of hereditary angioedema (HAE) with lab data confirming diagnosis: a. C1-INH and serum complement factor 4 level below the reference range along with a serum C1q level within normal reference range, OR b. C1-INH level that is normal or elevated but dysfunctional, low C4 level and normal C1q level, OR c. Normal C1-INH with normal functional assay and normal C4 and C1q levels. Must have family history of HAE
Age Restrictions	Cinryze-6 years and older, Ruconest-13 years and older
Prescriber Restrictions	Allergist, immunologist or hematologist
Coverage Duration	6 months initial, extension 12 months
Other Criteria	Documentation that triggers of attacks have been prophylactically treated appropriately with attenuated androgens, and aminocaproic acid or tranexamic acid and HAE attacks persist. Ruconest will only be approved for the treatment of acute attacks and for extensions of therapy documentation must identify decreased severity and duration of attacks and decreased hospitalization. Cinryze will only be approved for prophylaxis against HAE attacks and for extensions of therapy documentation must identify a decrease in hospitalizations or emergency room visits compared to previous therapy.

Prior Authorization Group	HETLIOZ
Drug Names	HETLIOZ
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation that the patient is totally blind. Diagnosis of Non-24-hour Sleep-Wake Disorder Circadian rhythm sleep-wake disorder, Non-24-hour sleep wake type or Circadian rhythm sleep disorder, free-running type. Sleep disturbance cannot be explained by other current sleep disorder, medical or neurological disorder, mental disorder, medication use or substance use disorder
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	3 months initial, extension 12 months
Other Criteria	Patient must have history of insomnia, excessive daytime sleepiness or both, which alternate with asymptomatic episodes.

Prior Authorization Group	HORMONAL ANTINEOPLASTIC AGENTS
Drug Names	ERLEADA, YONSA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of diagnosis, current chart notes and any previous and concurrent therapies
Age Restrictions	-
Prescriber Restrictions	Oncologist
Coverage Duration	12 months
Other Criteria	-

Prior Authorization Group	HUMIRA
Drug Names	HUMIRA, HUMIRA PEDIATRIC CROHNS D, HUMIRA PEN, HUMIRA PEN-CD/UC/HS START, HUMIRA PEN-PS/UV STARTER
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Frequency/dose not greater than 40mg every other week except for the initial 2-week induction period for Crohn's Disease or Ulcerative colitis and plaque psoriasis OR for rheumatoid arthritis after a failure of every other week dosing. For arthritis, Prior trial with mtx unless documentation of acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease. Chart notes including physical exam findings, number of swollen or tender joints, duration of morning stiffness, other symptoms, requested dose and frequency and expected duration of therapy. For Crohn's disease and Ulcerative colitis: response to or an intolerance to conventional therapy . Assessment of growth, nutrition, therapy-induced complications and functional ability. Clinical signs and symptoms such as frequency of stools, severity grade and frequency of abdominal pain, presence of an abdominal mass, extra-intestinal symptoms, prescription history, and current and past weights. For psoriasis: %BSA involvement current and with extension of therapy, previous and current therapies and responses. For a diagnosis of AS, chart notes including status of back pain and spinal mobility. For Psoriatic arthritis: chart notes including number of tender and swollen joints, previous therapies, diagnosis of psoriasis or family history (diagnosis in a first or second degree relative) of psoriasis.
Age Restrictions	-
Prescriber Restrictions	Restricted to rheumatologists or immunologists for members with arthropathies, dermatologists, gastroenterologists, colorectal surgeons, ophthalmologist
Coverage Duration	12 months
Other Criteria	A. For moderate-severe active adult RA w/synovitis and AM stiffness of significant duration to inhibit ADLs, the following must be met:Failed to respond to 1 or more nonbiologic DMARDs, 1 of which is an adequate trial of max tolerated dose of MTX.If the member has contraindication or intolerance to MTX, then must have failed to respond to an adequate trial of 1 other DMARD at a maximally tolerated dose for at least 3 months. B. For moderate-severe JIA as indicated by 5 swollen joints and 3 or more joints w/limitation of motion, pain, tenderness or both, or persistent symptoms, the following must be met: Failed to respond to an adequate trial of 1 DMARD. C. For the trmt of moderate-severe PsA as indicated by 3 or more tender joints AND 3 or more swollen joints on 2 separate occasions at least 1 month apart, the following must be met: Must have had an inadequate response to 1 NSAID, and Failed to respond to an adequate trial of at least 1 DMARD. D. Humira for Plaque psoriasis will be considered when ALL of the following are met: Moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp. An appropriate trial was not effective or contraindicated with one of the following: MTX, oral retinoids, cyclosporine. E: For

AS:failure during a 3 month period of 1 NSAID at max tolerated dose and BASDAI greater than or equal to 4, Failure of a 12 week trial of sulfasalazine at max tolerated dose in patients with persistent peripheral arthritis, no trial of DMARDs required for pure axial manifestations. F. Criteria for confirmed Crohn's and UC: all of the following must be met: intolerance to 2 different drug classes (e.g. corticosteroids and immunomodulators such as AZA or 6-MP), clinical signs and symptoms such as frequent liquid stools greater than 4/day, presence of abdominal pain, need for opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss greater than 10%. Concomitant therapy with Rituxan, biologic or targeted therapies will not be covered. Continuation of therapy for all indications will require documentation of improvement of clinical signs and symptoms.

Prior Authorization Group

ILARIS

Drug Names

ILARIS

Covered Uses

All FDA-approved indications not otherwise excluded from Part D

Exclusion Criteria

-

Required Medical Information

For Cryopyrin-Associated Periodic Syndromes (CAPS): Documentation of laboratory results identifying a mutation in Cold Autoinflammatory Syndrome gene -NLRP3 (CIAS1) AND: Familial Cold Auto-Inflammatory Syndrome (FCAS): Recurrent intermittent episodes of fever and rash that develops within 1-2 hours after natural or artificial (e.g., air conditioning) generalized cold exposure, Start of symptoms in early infancy or early childhood. OR Muckle-Wells Syndrome: Symptoms of fever with the other symptoms (joint pain, headaches, eye inflammation) usually last 1-2 days, and can be triggered at random, or sometimes by cold temperatures, stress or exercise. If there has been any hearing loss or amyloidosis. For Systemic Juvenile Idiopathic Arthritis (SJIA): Documented disease activity for 6 months, Chart notes identifying synovitis and number of swollen and/or tender joints

Age Restrictions

CAPS -4 years of age and greater, SJIA-2 years of age and greater

Prescriber Restrictions

Rheumatologist, immunologist or dermatologist

Coverage Duration

Initial 4 months with 12 month extensions

Other Criteria

For Systemic Juvenile Idiopathic Arthritis: Documentation must include failure or inadequate response to a 1 month trial of Kineret and a 12 week trial of Actemra. If chart notes identify intolerance, and/or clinical side effects, and/or contraindication to Kineret and Actemra, the following must be documented: Failed to respond to an adequate trial of maximally tolerated dose of methotrexate or leflunomide. For Cryopyrin-Associated Periodic Syndromes: failure or inadequate response to a 12 weeks trial of Kineret

Prior Authorization Group

Drug Names

IMMUNOGLOBULIN THERAPY

BIVIGAM, CARIMUNE NANOFILTERED, FLEBOGAMMA DIF, GAMASTAN S/D, GAMMAGARD LIQUID, GAMMAGARD S/D IGA LESS TH, GAMMAKED, GAMMAPLEX, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

Covered Uses

All FDA-approved indications not otherwise excluded from Part D AND the following for intravenous form only: 1. chronic inflammatory demyelinating polyneuropathy, 2. Idiopathic Thrombocytopenia Purpura (ITP), 3. bone marrow transplant patients at risk for septicemia, 4. interstitial pneumonia, 5. idiopathic infections, 6. graft vs. host disease (GVHD) or cytomegalovirus (CMV), 7. HIV infected children, 8. B-cell chronic lymphatic leukemia (CLL), 9. Guillian-Barre syndrome, 10. relapsing-remitting MS, 11. myasthenia gravis with acute severe decompensation, 12. Kawasaki disease, 13. autoimmune mucocutaneous blistering diseases, 14. recurrent severe infection with documented severe deficiency or absence of IgG subclass, 15. clinically significant functional deficiency of humoral immunity, 16. solid organ transplantation. 17. Acute and chronic inflammatory demyelinating polyradiculoneuropathy. 18. ITP in pregnancy. 19. Humoral or vascular allograft rejection. 20. Polymyositis and dermatomyositis. 21. sensitized renal cell transplant patients.

Exclusion Criteria

Required Medical Information

-
Myasthenia gravis w/ acute severe decompensation when 2 standard trtmts such as pyridostigmine and steroids failed. HIV infected child with CD4 more than 200u/L. Recurrent severe inf w/ severe def or absence of IgG. Clinically significant functional def of humoral immunity as evidenced by failure to produce antibodies to specific antigens and a h/o of recurrent inf. Solid organ transplant if transplant was for a MVP covered indication and the patient was CMV sero-neg pre transplantation and the donor is sero-positive. ITP in pregnancy if: pregnant who have previously delivered infants w/ autoimmune thrombocytopenia, have PLT counts less than 75,000/mm³ during the current pregnancy, or past hx of splenectomy. Polymyositis and dermatomyositis: unresponsive or intolerant to steroids and immunosuppressants. IVIG will be used to decrease the doses of other drugs that are needed for trmt. Must show that there was a measurable response w/i 6 months, or its use will no longer be covered. Sensitized renal cell transplant: IVIG and/or plasmapheresis are used in several sequential trmts pre or post-transplant to help w/ pts sensitized to living or cadaveric donors. This attempts to modify PRA level, a cross match result, with prevention and/or trmt of organ rejection) Kawasaki fever within 7 days. Hypogammaglobulinemia and B-cell CLL undergoing allogeneic BMT and at risk for septicemia. Autoimmune mucocutaneous blistering diseases, interstitial pneumonia in post-BMT patients: failure of steroids. Idiopathic infections: 3 hospitalizations w/i past 12 months d/t infections AND low IgG GVHD, CMV: use in BMT patients. Guillian-Barre syndrome, Hemolytic uremic syndrome: failure of plasma exchange. RRMS after failure of methylpred and Copaxone or interferon. Polyradiculoneuropathy: failure of 2 therapies such as steroids and azathioprine or MTX. ITP in pregnancy: IVIG can be used first line

Age Restrictions

Prescriber Restrictions

Coverage Duration

Other Criteria

with corticosteroids. Humoral or vascular allograft rejection: can be used first line. IVIG restricted as per the package label.

-
Initial approval 3 months with extension of 6 month intervals.

IVIG may be covered under Medicare Part B or D depending upon the circumstances. When covered under Part B, IVIG is not covered under Part D. Information may need to be submitted describing the use and setting of the drug to make the determination.

Prior Authorization Group

Drug Names

INTRAVENOUS (IV) VS. ORAL
CIPROFLOXACIN, CIPROFLOXACIN I.V.-IN D5W, GRANISETRON HCL, LEVOFLOXACIN, LEVOFLOXACIN IN D5W, LINEZOLID, ONDANSETRON HCL
All FDA-approved indications not otherwise excluded from Part D.

Covered Uses

Exclusion Criteria

Required Medical Information

-
Medical information identifying that the patient was unable to tolerate the oral preparation prior to initiation of the intravenous form of the medication. Medical information must include ONE of the following: For any medication under this prior authorization group including anti-emetics: 1. patient suffers from esophageal cancer and cannot swallow, 2. patient has had recent head and neck irradiation and has severe mucositis and cannot swallow, 3. patient is already suffering from clinically significant severe nausea and vomiting when the medication is needed, 4. Radiologic reports indicating non-functional gastrointestinal tract (e.g. short gut syndrome), 5. Chart notes identifying the rationale for using an intravenous medication, when there is an equivalent oral medication available for all other instances will be reviewed on a case-by-case when scientific studies are provided identifying that only the intravenous version is appropriate. For anti-emetics: one of the above criteria (1-5) OR one criteria below (6 or 7) needs to be met. 6. an appropriate oral anti-emetic drug failed to prevent chemotherapy induced nausea and vomiting at the maximum dosage and frequency. The intravenous formulation must be the same as the failed oral drug. If the IV formulation requested is of a different drug, then the oral formulation of that different drug must be shown to be ineffective or contraindicated before the IV form is covered. 7. Scientific studies of chemotherapy regimens identifying only the IV form of the anti-emetic drug where proven to be effective. However if the studies show that both oral and IV forms are effective, then the oral drug would need to be tried.

Restricted to FDA approved package labeling age restrictions.

Age Restrictions

Prescriber Restrictions

Coverage Duration

Other Criteria

-
Initial 3-month trial to evaluate outcomes. Approval in 6-month intervals thereafter.

These drugs 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(s) to make the determination. Only covered for FDA approved indications not otherwise excluded from Part D. For continuation of the injectable version, chart notes must identify a better response than the oral product.

Prior Authorization Group	ITRACONAZOLE
Drug Names	ITRACONAZOLE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D and the following: tinea corporis, cruris or pedis
Exclusion Criteria	Congestive heart failure
Required Medical Information	For onychomycosis: Positive KOH test from a nail scraping or a positive pathogenic fungal culture documenting the presence of hyphae consistent with susceptible dermatophytes (tinea unguium). Member is non-immunocompromised (e.g. negative HIV status, not undergoing chemotherapy, not a transplant recipient). Identify location of onychomycosis (e.g. fingernails and/or toenails). For lung fungal infections, start date of itraconazole and: Fungal cultures identifying one of the following 1. Blastomycosis. 2. Histoplasmosis. 3. Aspergillosis.
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	Onychomycosis-12 weeks, all other indications-12 months
Other Criteria	For onychomycosis infection: failure or contraindication to terbinafine. For aspergillosis fungal infection: failure or contraindication to amphotericin B therapy. For tinea corporis, cruris or pedis: failure or contraindication to ketoconazole cream and econazole cream. Combination therapy with more than one antifungal agent (terbinafine, itraconazole, ciclopirox) will not be covered

Prior Authorization Group	JAKAFI
Drug Names	JAKAFI
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Chronic myelogenous leukemia, myelodysplastic syndrome, or other myeloid neoplasm.
Required Medical Information	Documentation provided supporting the diagnosis of intermediate or high-risk myelofibrosis including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. Baseline Modified Myelofibrosis Symptom Assessment Form (mMFSAF) total symptom score. Prognostic factors based on the International Working Group Consensus Criteria: Age greater than 65 years old, White blood cell count greater than 25 x 10 to the 9th /L, Hemoglobin less than 10 g/dL, Peripheral blood blast greater than or equal to 1 percent, Positive for constitutional symptoms (e.g. fatigue, weight loss, night sweats, and bone pain). For continuation of therapy: decrease in symptoms vs baseline MFSAF total symptom score. For Polycythemia vera: documented diagnosis of polycythemia vera.
Age Restrictions	18 years old and older
Prescriber Restrictions	Oncologists
Coverage Duration	12 months
Other Criteria	For Polycythemia Vera must have inadequate response or intolerance to hydroxyurea

Prior Authorization Group	JUXTAPID
Drug Names	JUXTAPID
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy. Concomitant use with strong or moderate CYP3A4 inhibitors. Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests.
Required Medical Information	Diagnosis of homozygous familial hypercholesterolemia. Baseline ALT, AST, alkaline phosphatase, and total bilirubin. Baseline cholesterol panel. Continuation of therapy will be considered if there is a decrease in LDL cholesterol from baseline.
Age Restrictions	18 years old and older
Prescriber Restrictions	Cardiologist, Lipidologist or Endocrinologist
Coverage Duration	Initial approval-6months. Extensions-remainder of contract year
Other Criteria	Failure to achieve goal LDL-C a 1 month trial with the combination of the maximally tolerated dose of a High-dose statin and Zetia (ezetimibe) unless contraindicated.

Prior Authorization Group	JYNARQUE
Drug Names	JYNARQUE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History, signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease), use in combination with strong CYP3A inhibitors, inability to sense or respond to thirst, uncorrected abnormal blood sodium concentrations, hypovolemia, hypersensitivity to tolvaptan, urinary outflow obstruction, anuria, patients who have progressed to end-stage renal disease.
Required Medical Information	Diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by ultrasound. Total kidney volume (TKV) classification of 1C or higher. Chart notes identifying symptoms of ADPKD such as hypertension and flank pain. Blood sodium concentrations, ALT, AST, and bilirubin levels prior to starting therapy.
Age Restrictions	18 years and older
Prescriber Restrictions	Ordered by or Consult with nephrologist
Coverage Duration	3 months. Extended authorizations limited to 6 months
Other Criteria	For continuation of therapy, documentation must be provided of continued monitoring of AST, ALT, and bilirubin monthly for 18 months and every 3 months thereafter. Prescribers must enroll in the REMS Access program.

Prior Authorization Group	KALYDECO
Drug Names	KALYDECO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of:Diagnosis of cystic fibrosis (CF). Identification that there is one mutation in the CFTR gene that is responsive to invacaftor based on clinical and or vitro assay data. For continuation of therapy, documentation provided must identify continued benefit supported by one of the following : Improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1, decrease in pulmonary exacerbations or improvement in CF symptoms including cough, sputum production, and difficulty breathing.
Age Restrictions	2 years and older
Prescriber Restrictions	Pulmonologist
Coverage Duration	6 months
Other Criteria	More than 60 tablets per 30 days are not covered.
Prior Authorization Group	KINASE INHIBITORS
Drug Names	AFINITOR, AFINITOR DISPERZ, ALECENSA, ALIQOPA, ALUNBRIG, BOSULIF, BRAFTOVI, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, ICLUSIG, IMATINIB MESYLATE, IMBRUVICA, INLYTA, IRESSA, LENVIMA 10 MG DAILY DOSE, LENVIMA 12MG DAILY DOSE, LENVIMA 14 MG DAILY DOSE, LENVIMA 18 MG DAILY DOSE, LENVIMA 20 MG DAILY DOSE, LENVIMA 24 MG DAILY DOSE, LENVIMA 4 MG DAILY DOSE, LENVIMA 8 MG DAILY DOSE, LORBRENA, MEKINIST, MEKTOVI, NERLYNX, NEXAVAR, RYDAPT, SPRYCEL, STIVARGA, SUTENT, TAGRISSO, VITRAKVI, VIZIMPRO, XALKORI, XOSPATA, ZELBORAF, ZYKADIA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of diagnosis, current chart notes and any previous and concurrent therapies
Age Restrictions	-
Prescriber Restrictions	Oncologist, transplant specialist, neurologist, or hematologist
Coverage Duration	12 months
Other Criteria	-

Prior Authorization Group	KORLYM
Drug Names	KORLYM
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Documentation of the diagnosis of Crushing's syndrome and that patient has failed surgery or is not a candidate for surgery. Current HbA1c level identifying glucose intolerance
Age Restrictions	18 years and older
Prescriber Restrictions	Endocrinologist
Coverage Duration	Initial 3 month approval, extensions 6 months.
Other Criteria	For continuation of therapy there must be a decrease in the HbA1c level from baseline
Prior Authorization Group	KUVAN
Drug Names	KUVAN
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	The use of Kuvan will not be considered medically necessary for the following situations:Diagnosis other than PKU with Hpa due to BH4-, Doses above 20mg/kg/day. Non-responders (i.e. do not have a decrease in blood Phe with Kuvan treatment after one month of treatment at the maximum dose).Not maintaining Phe levels below baseline. Previous failure of Kuvan.
Required Medical Information	Documentation must be provided for all of the following: Dx of PKU and current mean blood Phe concentration above the upper limit of the recommended ranges which are: Infants less than 1 year of age: 120-360 mol per L. Patients greater than or equal to 2 years of age including pregnant women: 60-360mol per L.. Greater than 12 yo: 2-10mg/dL (120 to 605 micromol per L). If the patient has been using the medication prior to the initial MVP request, the above criteria must have been met prior to initiation and evidence demonstrating a clinically relevant decrease from the baseline mean blood Phe conc after 1 month of Kuvan 20mg/kg/day must be documented in the medical record. Extension of therapy will be considered if documentation supports: mean blood Phe concentration with a clinically significant decrease of blood Phe from mean pretreatment levels continues.
Age Restrictions	-
Prescriber Restrictions	Specialist or prescriber with experience in PKU
Coverage Duration	2 months initial approval, extension 6 months
Other Criteria	-

Prior Authorization Group	KYNAMRO
Drug Names	KYNAMRO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Moderate or severe hepatic impairment, or active liver disease, including unexplained persistent elevations of serum transaminases, known sensitivity to product components
Required Medical Information	Diagnosis of homozygous familial hypercholesterolemia. Baseline ALT, AST, alkaline phosphatase, and total bilirubin. Baseline cholesterol panel. Continuation of therapy will be considered if there is a decrease in LDL cholesterol from baseline
Age Restrictions	18 years old and older
Prescriber Restrictions	Cardiologist, Lipidologist or Endocrinologist
Coverage Duration	Initial approval 6 months, extensions up to 12 months
Other Criteria	Failure to achieve goal LDL-C despite a 1 month trial of a combination of two of the following: High-dose statin, Bile acid sequestrant or Zetia (ezetimibe). Patient must not be receiving LDL apheresis

Prior Authorization Group	LAZANDA
Drug Names	LAZANDA
Covered Uses	All FDA-approved indications not otherwise excluded from part-D.
Exclusion Criteria	Management of acute or postoperative pain, including dental pain, or headache/migraine. Management of pain in patients who are non-opioid tolerant. Intolerance or hypersensitivity to fentanyl
Required Medical Information	Diagnosis of cancer. Documentation of intended use for breakthrough cancer pain. Documentation of current opioid use for one week or longer which equals or surpasses: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or any equianalgesic dose of another opioid. Documentation of failure of greater than 1 immediate release opioid or contraindication to the use of oral immediate release products. Extension of therapy requires documentation of: continued benefit from therapy and optimized long-acting opioid therapy at maximum tolerated dose
Age Restrictions	18 years old and older
Prescriber Restrictions	Oncologist, Anesthesiologist, Hopsice Palliative Care specialist, or pain management specialist
Coverage Duration	Initial 3 months approval followed by 6 months intervals
Other Criteria	Patients must: Remain on chronic long acting opioid therapy and continue to meet the definition of opioid tolerance while taking Lazanda and show ineffective relief from immediate-release opioids by excessive rescue doses despite optimal long-acting opioid therapy. Prescribers must enroll in the TIRF REMS Access program

Prior Authorization Group	LETAIRIS
Drug Names	LETAIRIS
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Use in pregnancy or for the treatment of idiopathic pulmonary fibrosis. Coverage will not be provided for: more than 1 tablet per day, or for the treatment of digital ulcers or erectile dysfunction. Combination therapy with other PAH agents will not be covered for initial therapy
Required Medical Information	Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying: resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients.(Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of therapy is dependent upon documentation of clinical response
Age Restrictions	18 years old and older
Prescriber Restrictions	Ordered by or Consult with pulmonologist or cardiologist
Coverage Duration	Initial authorization will be limited to 3 months. Extended authorizations limited to 12 months
Other Criteria	-
Prior Authorization Group	LIDOCAINE PATCH
Drug Names	LIDOCAINE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D and diabetic neuropathy
Exclusion Criteria	Hypersensitivity to local anesthetics of the amide type (like prilocaine or bupivacaine).
Required Medical Information	Documentation of diagnosis of post-herpetic neuralgia or diabetic neuropathy.
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	Documentation must identify diagnosis of the post-herpetic neuralgia or diabetic neuropathy. Continuation of therapy will require documentation of improvement in the clinical signs and symptoms described.

Prior Authorization Group	LIDOCAINE TOPICAL
Drug Names	LIDOCAINE, LIDOCAINE HCL, LIDOCAINE HCL JELLY
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Documentation of diagnosis for use
Age Restrictions	-
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	-
Prior Authorization Group	MEGESTROL
Drug Names	MEGESTROL ACETATE
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Current chart notes and diagnosis of use
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	Non-FDA approved diagnosis will be evaluated according to the CMS medically accepted indications requirements in Chapter 6 of the Medicare Prescription Drug Benefit Manual
Prior Authorization Group	MODAFINIL
Drug Names	ARMODAFINIL, MODAFINIL
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Condition modafinil or armodafinil is being used to treat. Narcolepsy with Excessive Daytime Sleepiness indication the following is required: Sleep Latency Test results. Obstructive Sleep Apnea indication the following are required: Polysomnography results
Age Restrictions	17 years old and older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	Narcolepsy with Excessive Daytime Sleepiness-patients must have had a positive Multiple Sleep Latency Test (MSLT). Obstructive Sleep Apnea-patients must have had a positive Polysomnography. For Shift Work Sleep Disorder the patient's symptoms should not be attributable to any co-morbid medical or mental condition. Continuation of therapy will require documentation of improvement in alertness or relevant clinical sign/symptom. Non-FDA approved diagnosis will be evaluated according to the CMS medically accepted indications requirements in Chapter 6 of the Medicare Prescription Drug Benefit Manual

Prior Authorization Group	MULPLETA
Drug Names	MULPLETA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation that the patient has chronic hepatic disease, date of upcoming procedure, platelet count prior to the procedure
Age Restrictions	-
Prescriber Restrictions	Ordered by or Consult with a Gastroenterologist, Hepatologist, or Hematologist
Coverage Duration	4 weeks
Other Criteria	-
Prior Authorization Group	MYALEPT
Drug Names	MYALEPT
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Hypersensitivity to metreleptin. General obesity not associated with congenital leptin deficiency
Required Medical Information	Documentation of: Diagnosis (noting generalized/partial, and congenital/acquired), Serum leptin level, Baseline triglyceride level, Baseline HbA1c level, Baseline fasting glucose level, Patient's current weight.
Age Restrictions	-
Prescriber Restrictions	-
Coverage Duration	Initial approval 6 months, extensions 12 months
Other Criteria	To be eligible for approval of Myalept therapy the patient must NOT have any of the following: Partial lipodystrophy, HIV-related lipodystrophy, Nonalcoholic Steatohepatitis (NASH), History of positive anti-metreleptin antibodies, General obesity in absence of generalized lipodystrophy, Diabetes Mellitus in absence of generalized lipodystrophy, Or hypertriglyceridemia in absence of generalized lipodystrophy. AND to be eligible for approval of Myalept therapy the patient MUST have all of the following: Clinical lipodystrophy (i.e. loss/absence of subcutaneous fat, insulin resistance, hypertriglyceridemia), Pharmacologic treatment of hypertriglyceridemia has been maximized or cannot be tolerated, Insulin therapy for the treatment of hyperglycemia has been maximized. For continued therapy: Documentation of response to Myalept must be provided with each request for extension of therapy that identifies improvement in the HbA1c, triglycerides and fasting glucose from baseline.

Prior Authorization Group	NAGLAZYME
Drug Names	NAGLAZYME
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	The use of Naglazyme will not be considered medically necessary for the following situations: Dose and/or frequency outside of package labeling
Required Medical Information	Naglazyme may be considered medically necessary if all of the following criteria are met: Documentation identifying diagnosis of MPS VI based on urine test identifying excess mucopolysaccharides AND enzyme assays testing a variety of cells or body fluids in culture for enzyme deficiency. 12-minute walk test between 5 and 400 meters. Extension of therapy will be considered if documentation identifies continued benefit based on improvement vs baseline and continued stability of the 12-minute walk test.
Age Restrictions	-
Prescriber Restrictions	-
Coverage Duration	Initial approval 6 months, extensions 12 months
Other Criteria	-
Prior Authorization Group	NATPARA
Drug Names	NATPARA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Diagnosis of hypoparathyroidism. Documentation of sufficient 25-hydroxyvitamin D stores and a corrected serum calcium above 7.5mg/dL before initiated therapy. Serum calcium and 25-hydroxyvitamin D levels with each extension request.
Age Restrictions	18 years old and older
Prescriber Restrictions	Endocrinologist
Coverage Duration	3 months initial, extension 12 months
Other Criteria	For extensions of therapy must maintain a corrected serum calcium concentration between 7.5 and 10.6 mg/dL

Prior Authorization Group	NOXAFIL
Drug Names	NOXAFIL
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation that member is at risk of developing invasive Aspergillus or Candida infection due to being severely immunocompromised (i.e. HSCT recipient with GVHD, hematologic malignancy with prolonged neutropenia from chemotherapy) or documentation of an oropharyngeal candidiasis infection
Age Restrictions	13 years and older
Prescriber Restrictions	-
Coverage Duration	Oropharyngeal candidiasis-2 weeks, aspergillus prophylaxis-3 months
Other Criteria	For aspergillus or candida prophylaxis must have failed therapy with or have a contraindication of voriconazole. For oropharyngeal candidiasis infection must have failed therapy with or have contraindication to fluconazole and voriconazole
Prior Authorization Group	NUEDEXTA
Drug Names	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 reaction. Hypersensitivity to dextromethorphan. Use with 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 AV block without implanted pacemaker, or patients at high risk of complete AV block. Concomitant use of drugs that both prolong QT interval and are metabolized by CYP2D6
Required Medical Information	Diagnosis of pseudobulbar affect (PBA) . Chart notes for the previous 3 months identifying the member's frequency of laughing and crying episodes. Center of Neurologic Studies Liability Scale (CNS-LS) score of greater than 13
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	Initial approval 3 months, extensions 12 months
Other Criteria	Extensions of therapy will be based on improvement in frequency of laughing and crying episodes and CNS-LS score from baseline

Prior Authorization Group	NUPLAZID
Drug Names	NUPLAZID
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of a diagnosis of Parkinson's disease for at least one year and severity and frequency of hallucinations and/or delusions
Age Restrictions	18 years and older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	Hallucinations and/or delusions must have started after the diagnosis of Parkinson's disease. Will not be covered for dementia-related psychosis
Prior Authorization Group	ODOMZO
Drug Names	ODOMZO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Diagnosis of locally advanced basal cell carcinoma (BCC), having recurred following surgery or radiation therapy or not being a candidate for surgery or radiation therapy.
Age Restrictions	18 years and older
Prescriber Restrictions	Oncologist
Coverage Duration	12 months
Other Criteria	Basal cell carcinoma must have recurred following surgery or radiation therapy or the patient is not a candidate for surgery or radiation therapy.
Prior Authorization Group	OFEV
Drug Names	OFEV
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documented diagnosis of idiopathic pulmonary fibrosis (IPF), HRCT results identifying the presence of a usual interstitial pneumonia (UIP) pattern, Lung biopsy confirming UIP if available, PE findings and liver function tests. For continued therapy: clinical response to OFEV must be provided with each request for extension of therapy
Age Restrictions	18 year and older
Prescriber Restrictions	Ordered by, or by consult with, a pulmonologist.
Coverage Duration	6 months
Other Criteria	Must have FVC greater than or equal to 50% of predicted and a carbon monoxide diffusing capacity of 30 to 70% of predicted prior to start of therapy. Must rule out other causes of interstitial lung disease such as domestic and occupational environmental exposures, connective tissue disease and /or drug toxicity. For documentation of therapy documentation must identify improvement or maintenance of disease (less than a 10% decline in FVC).

Prior Authorization Group	OPSUMIT
Drug Names	OPSUMIT
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Pregnancy. Coverage will not be provided for the following: treatment of digital ulcers, or dosing exceeding FDA approved package label. Combination therapy with other PAH agents will not be covered for initial therapy.
Required Medical Information	If WHO Group I verification of pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying: resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg.. If WHO Group 4, verification of CTEPH diagnosis via ventilation-perfusion scanning and confirmatory pulmonary angiography AND Documentation of persistence/recurrence of CTEPH following surgical treatment OR Documentation that indicates patient is not considered a surgical candidate for the treatment of CTEPH. If WHO Group 1, vasoreactive testing is recommended for all PAH patients (documentation with rationale must be provided for patients for whom this testing is not performed). Documentation of previous and current therapies identifying outcome. Extension of therapy will be dependent upon documentation of clinical response.
Age Restrictions	18 years old and older
Prescriber Restrictions	cardiologist or pulmonologist
Coverage Duration	Initial authorization will be limited to 3 months. Extension up to 12 months
Other Criteria	Documentation must include failure or inadequate response to an adequate trial of Letairis (for new starts only).
Prior Authorization Group	ORKAMBI
Drug Names	ORKAMBI
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Chart notes identifying diagnosis of cystic fibrosis and test results identifying a homozygous F508del mutation in the CFTR gene. Baseline ppFEV1 results, BMI and number of pulmonary exacerbations in the past 6 months.
Age Restrictions	2 years old and older
Prescriber Restrictions	Pulmonologist
Coverage Duration	6 months
Other Criteria	For extension of therapy member must meet one of the following: 1. stabilization or improvement in ppFEV1 from baseline 2. Increase in BMI from baseline 3. Decrease in the number of pulmonary exacerbations from baseline

Prior Authorization Group	PRALUENT
Drug Names	PRALUENT
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Members has one of the following conditions: 1)Prior clinical atherosclerotic cardiovascular disease (ASCVD) (see Other Criteria), or 2)Heterozygous familial hypercholesterolemia (HeFH). For member s with ASCVD at least one of the following is met: 1)Current LDL-C 70mg/dL or greater after 3 months of treatment with optimized lipid-lowering therapy (see Other Criteria), 2)Current LDL-C 70mg/dL or greater with contradiction(CI) to statin or intolerance to statin(see Other Criteria), 3)Currently LDL-C 70mg/dL or greater with CI to statin (see Other Criteria). For members with HeFH at least one of the following is met: 1)Current LDL-C 100mg/dL or greater after at least 3 months of treatment with optimized lipid-lowering therapy(see Other Criteria), 2)Current LDL-C 100mg/dL or greater with CI or intolerance to statin (see Other Criteria), 4)Current LDL-C 100mg/dL or greater and CI to statin (see Other Criteria). For continuation: Response to therapy as demonstrated by a reduction in LDL-C 18 years old and older
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	Clinical ASCVD defined as acute coronary syndromes, myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, or findings from a CT angiogram or catheterization consistent with clinical ASCVD. Diagnosis of HeFH must be confirmed by one of the following: 1)Genetic confirmation, 2)Simon-Broome Diagnostic criteria: total cholesterol greater than 290mg/dL or LDL-C greater than 190mg/dL plus tendon xanthomas in first or second degree relative, or 3) Dutch Lipid Clinic Network total score greater than 8 points. Diagnosis of HeFH must be confirmed by Lipidologist, Endocrinologist or Cardiologist specializing in lipid management. Optimized lipid lower treatment is defined as: 1)Atorvastatin 40mg or greater, or 2)Rosuvastatin 20mg or greater. Members with a history of intolerance to statin must meet one of the following: 1)Intolerable muscle pain persisting at least 2 weeks where pain resolves upon stopping statin. Must re-challenge with original statin or rosuvastatin. 2)Statin-associated elevation in creatine kinase(CK) level greater than or equal to 5 times UL that resolves upon discontinuation of statin. 3) Statin-associated rhabdomyolysis. Contraindication to statin must be due to one of the following: 1)Active liver disease or unexplained persistent elevations in serum transaminases (3 times ULN), or 2)Women who are pregnant or may become pregnant, or 3) Nursing mothers. Starting dose will be 75mg every 2 weeks

Prior Authorization Group	PROMACTA
Drug Names	PROMACTA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	PROMACTA will not be covered under Part D if used in an attempt to normalize platelet counts.
Required Medical Information	Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin prior to initiation of PROMACTA, every 2 weeks during the dose adjustment phase and monthly following establishment of a stable dose. Documentation whether member has had a splenectomy. For Diagnosis of chronic immune idiopathic thrombocytopenia purpura and severe aplastic anemia: CBC with differential with Platelet count less than $30 \times 10^9/L$. Outcome and length of previous therapies such as IVIG, corticosteroids, cytotoxic therapies, danazol, and azathioprine. For thrombocytopenia in patients with chronic hepatitis C to allow initiation and maintenance of interferon-based therapy: Documentations that the patient is eligible to receive interferon-based therapy. CBC with differential with Platelet count less than $75 \times 10^9/L$. Outcomes of any previous therapies such as splenic artery embolization, splenectomy or TIPS.
Age Restrictions	6 years old and older
Prescriber Restrictions	Hematologist and hepatologist
Coverage Duration	Initial approval will be for 3 months. Extension of therapy up to one year.
Other Criteria	For Diagnosis of chronic immune idiopathic thrombocytopenia purpura and severe aplastic anemia: Degree of thrombocytopenia and clinical condition puts member at increase risk of bleeding, AND Failure or contraindication to two of the following: 1. IVIG (if newly diagnosed), 2. corticosteroids, 3. splenectomy. For Diagnosis of thrombocytopenia in patients with chronic hepatitis C: Degree of thrombocytopenia does not allow member to start interferon-based therapy. Other therapies such as splenic artery embolization, splenectomy or TIPS would not be clinically appropriate. Continuation of therapy: Platelet count must not exceed $400 \times 10^9/L$ after 2 weeks of therapy at lowest FDA approved dose. ALT levels must remain less than 3x upper limit of normal and are not progressive or persistent for greater than or equal to 4 weeks or accompanied by increased direct bilirubin, or clinical symptoms or liver injury or evidence for hepatic decompensation. Required adequate response with a platelet count of greater than $50 \times 10^9/L$. Platelet count must increase after 4 weeks at the maximum dose. For chronic hepatitis C to allow initiation and maintenance of interferon-based therapy: Requires adequate response with a platelet count of greater than $90 \times 10^9/L$. Platelet count must increase after 2 weeks at the maximum FDA approved dose. Severe Aplastic Anemia: platelet count must increase to $20 \times 10^9/L$ from baseline or stable platelet count with transfusion independence for a minimum of 8 weeks, or hemoglobin increases by greater than 1.5g/dL or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks, or ANC increase of 100% or an ANC increase greater than $0.5 \times 10^9/L$ after 12 weeks

of therapy

Prior Authorization Group

RAGWITEK

Drug Names

RAGWITEK

Covered Uses

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

Exclusion Criteria

Severe, unstable or uncontrolled asthma. History of eosinophilic esophagitis. History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy

Required Medical Information

Documented allergic rhinitis with or without conjunctivitis. Positive skin test or in vitro testing for pollen-specific IgE antibodies for the specific allergen extract OR a strongly cross-reactive allergen to the following: Pollen-specific IgE antibodies- Short Ragweed Pollen Allergen Extract, Strongly Cross-Reactive Allergen- Short, giant, western, and false ragweed. Allergen must be identified as the cause of the major clinical symptoms

18 through 65 years of age

Age Restrictions

Prescriber Restrictions

-

Coverage Duration

12 months

Other Criteria

Treatment must be initiated at least 12 weeks before expected pollen season based on geographic location (usually mid-August in Northeast). Therapy should be initiated by April in Northeast. Documentation must identify failure of at least two of the following treatments: Intranasal corticosteroids, oral antihistamine, or oral leukotriene receptor antagonist. For continuation of treatment, the benefits of treatment (decrease of symptoms, increase tolerance to grass pollen) must be documented in the member's chart. Extension will be through remainder of allergen season-typically October in Northeast. Will not be covered if receiving subcutaneous allergen immunotherapy

Prior Authorization Group	REMICADE
Drug Names	REMICADE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	No TB skin test result provided or TB infection has not been treated appropriately. Concomitant therapy with Rituxan and other DMARDs or biologic therapies other than MTX. Members with CHF with NYHA class III/IV at doses of greater than 5mg/kg.
Required Medical Information	RA:persistent or recurrent symptoms with synovitis and AM stiffness of significant duration to inhibit ADLs. For continued therapy:Achieving ACR 20 response AND demonstrated beneficial response. B. PsA:documentation at least 3 tender joints AND at least 3 swollen joints on 2 separate occasions at least 1 month apart. For RA and PsA:Continuation of tx requires a decrease in swollen or tender joints and duration of AM stiffness.C.Psoriasis: documentation of severe chronic plaque psoriasis with 10% BSA involvement OR involvement of the palms, soles of feet and scalp causing functional disability. Continuation of therapy will require documentation of improved patient status in the monitoring parameters of the following: A significant improvement of clinical S/S of psoriasis (e.g. itching, redness, scaling, psoriatic BSA coverage) at 3 months. QOL assessments improved per pt and/or MD. D. AS: chart notes including status of back pain and spinal mobility and BASDAI greater than or equal to 4. Continued coverage:significant symptom improvement and/or 2 units of the BASDI. E.Crohn's disease/UC:Significant clinical signs, symptoms, and radiologic reports documenting moderate to severely active disease such as frequent liquid stools greater than 4 times/day, presence of abdominal pain, presence of abdominal mass, extra-intestinal symptoms, need for opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss greater than 10%.Fistulizing Crohn's disease: present for at least 3 months.For continuation: documentation of improvement in symptoms.
Age Restrictions	Restricted to 18 years of age and older, except for Crohn's and ulcerative colitis which is restricted to 6 years and older.
Prescriber Restrictions	Restricted to rheumatologists, immunologists, dermatologists, gastroenterologists, colorectal surgeons
Coverage Duration	Initial approval for 3 months with extensions of up to 6 months intervals
Other Criteria	Must be screened for immunologic and infectious diseases including hepatitis and TB. A. RA:Documentation must include failure or inadequate response to a 12week trial each of Humira and Enbrel and given in combination with at least 12.5mg/week of mtx or maximum dose tolerable for the patient, OR If chart notes identify intolerance, and/or clinical side effects, and/or contraindication to Enbrel and Humira, the following must be documented:Failed to respond to an adequate trial of maximally tolerated dose of mtx. (Failure is defined as ACR response less than 20.)If the member has a contraindication or significant intolerance to mtx, the member must have failed to respond for an adequate trial to at least one other nonbiologic DMARDs at a maximally tolerated dose.B.Crohn's Disease and UC: Documentation must include failure or inadequate response to a 12week trial of Humira and one of the following:1. Corticosteroids, OR 2.

Anti-inflammatory aminosalicylates(e.g. sulfasalazine)OR if chart notes identify intolerance and/or clinical side effects and/or contraindication to Humira, a trial of both corticosteroids and anti-inflammatory aminosalicylates is required.C.For PsA, Plaque Psoriasis, and AS: Documentation must include failure or inadequate response to a 12week trial each of Humira and Enbrel, OR If chart notes identify intolerance, and/or clinical side effects, and/or contraindication to Enbrel and Humira, the following must be documented:PsA:Failed to respond to an adequate trial of one DMARD.Plaque Psoriasis: An appropriate treatment trial of two of the following agents was not effective: methotrexate, oral retinoids, cyclosporine. AS: Failure during a 3 month period of 1 NSAIDS at maximum tolerated dose and insufficient response to 1 local corticosteroid inj (peripheral arthritis), Failure of a 12week trial of sulfasalazine at maximum tolerated dose in patients with persistent peripheral arthritis.No trial of DMARDS required for pure axial manifestations. Members with Wegener's granulomatosis prior to failure of at least two of the following agents: azathioprine, cyclophosphamide, glucocorticoids, MTX. For continuation of coverage: clinical failure or less than desired effect with Remicade and no clinical rationale provided for continuation of therapy.

Prior Authorization Group

Drug Names

Covered Uses

Exclusion Criteria

Required Medical Information

Age Restrictions

Prescriber Restrictions

Coverage Duration

Other Criteria

RIBAVIRIN

RIBASPHERE, RIBAVIRIN

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

Contraindications for the use of ribavirin, including pregnancy, renal failure, hemoglobinopathies.

HCV RNA level and genotype

-

-

12 to 48 weeks for adults and 24 to 48 weeks for children based on genotype

Will not be approved as monotherapy for the treatment of hepatitis C. Criteria will be applied consistent with current AASLD/IDSA guidance

Prior Authorization Group	SAMSCA
Drug Names	SAMSCA
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Need to raise serum sodium acutely. Patients who are unable to respond appropriately to thirst. Hypovolemic hyponatremia. Concomitant use of strong CYP 3A inhibitors. Anuric patients. Patients with liver disease.
Required Medical Information	Documentation of the following: Evaluated for factors contributing to hyponatremia. Euvolemic (no edema) hyponatremia with Syndrome of Inappropriate Antidiuretic Hormone (SIADH) OR hypervolemic (edema) hyponatremia with heart failure or cirrhosis. Serum sodium less than 125 mEq/L OR hyponatremic with a serum sodium greater than or equal to 125 mEq/L AND symptomatic AND unable to restrict fluid due to documented disorder or condition that would limit compliance with fluid restriction. Tolvaptan must be initiated, titrated, and re-initiated in a hospital setting until stable. Unless contraindicated: failure of fluid restriction, saline infusion, drug therapy and/or sodium restriction (if indicated) or removal of offending medication. For continuation of therapy: Continued necessity of tolvaptan vs. standard of care therapies. Continued benefit from tolvaptan with stabilization of serum sodium to normal limits.
Age Restrictions	18 years old and older
Prescriber Restrictions	Endocrinologists, Nephrologists
Coverage Duration	Maximum of 30 days
Other Criteria	Patients with symptoms that may indicate liver injury should discontinue treatment with Samsca. Samsca should not be used longer than 30 days.

Prior Authorization Group	SILDENAFIL
Drug Names	SILDENAFIL
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage will not be provided for the treatment of digital ulcer or erectile dysfunction. Combination therapy will not be covered for initial therapy.
Required Medical Information	Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying: resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients. (Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of therapy is dependent upon documentation of clinical response
Age Restrictions	18 years old and older
Prescriber Restrictions	Ordered by or Consult with pulmonologist or cardiologist
Coverage Duration	Initial approval 4 months, extensions 12 months
Other Criteria	-

Prior Authorization Group	SYLVANT
Drug Names	SYLVANT
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Diagnosis of multicentric Castleman's disease confirmed by lymph node biopsy. Screening results for human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). CT or MRI result. Current chart notes identifying if peripheral lymphadenopathy, fever, or organomegaly are present
Age Restrictions	18 years old and older
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	6 months
Other Criteria	HIV and HHV-8 screening results must be negative. For continued therapy: Documentation of response to Sylvant must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms
Prior Authorization Group	TAKHZYRO
Drug Names	TAKHZYRO
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of the following must be provided: 1. Laboratory data confirming diagnosis of hereditary angioedema (HAE) with on of the following: a.C1-INH and serum complement factor 4 level below the reference range along with a serum C1q level within normal reference range, OR b. C1-INH level that is normal or elevated but dysfunctional, low C4 level and normal C1q level, OR c. Normal C1-INH with normal functional assay and normal C4 and C1q levels AND Family history of HAE, if any. 2. Medications that may trigger or worsen angioedema have been evaluated and discontinued if appropriate. (Examples of these are estrogen contraceptives, hormone replacement therapy, and ACE-Inhibitors.) 3. Member is not currently receiving medications that may trigger or worsen angioedema. 4. Member has a history of at 1 acute HAE attack per month. For continued use, the following documentation must be identified following Takhzyro use: diminished symptoms, decreased severity of attacks, reduced duration of attacks, and decreased hospitalizations when compared to previous therapies. Please provide date of last attack.
Age Restrictions	12 years and older
Prescriber Restrictions	Allergist, immunologist or hematologist
Coverage Duration	3 months. Extended authorizations limited to 6 months
Other Criteria	Not to be used in combination with Cinryze, or Haegarda. Triggers (e.g. surgery, major dental work, etc.) of attacks have been prophylactically treated appropriately and HAE attacks persist OR contraindication (such as pregnancy or lactation).

Prior Authorization Group	TEGSEDI
Drug Names	TEGSEDI
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of the following must be provided: 1. Patient has documented transthyretin (TTR) mutation as confirmed through genetic testing AND Presence of polyneuropathy characterized by ONE of the following: i. Baseline polyneuropathy disability (PND) score less than IIIb ii. Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2. 2. Patient has a platelet count greater than 100 x 10 ⁹ /L
Age Restrictions	18 years and older
Prescriber Restrictions	Neurologist, immunologist, or physician who specializes in the treatment of amyloidosis
Coverage Duration	3 months. Extended authorizations limited to 6 months
Other Criteria	For continuation of therapy, clinical documentation showing the patient has experienced a positive clinical response to Tegsedi (ie, improved neurologic impairment, motor function, cardiac function, quality of life assessment) must be identified.
Prior Authorization Group	TETRABENAZINE
Drug Names	TETRABENAZINE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use with reserpine or use of reserpine within the past 20 days. Members with liver disease.Uncontrolled or untreated depression.
Required Medical Information	Chart notes including:baseline and any subsequent total Chorea Score or the Unified Huntington's Disease Rating Scale (UHDRS), neurological exam, genetic testing confirming Huntington's disease. Documentation of functional disability due to chorea symptoms from Huntington's disease. For continuation of therapy, total Chorea Score improved at least 3.5 units since initiating tetrabenazine therapy or the chorea has significantly improved.
Age Restrictions	18 years old and older
Prescriber Restrictions	Restricted to neurologists
Coverage Duration	Initial approval for 3 months.Continuation of therapy six months.
Other Criteria	For doses above 50mg per day testing must be provided identifying patient is an extensive or intermediate metabolizer of CYP2D6

Prior Authorization Group	TOBI PODHALER
Drug Names	TOBI PODHALER
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Hypersensitivity to any aminoglycoside, Forced expiratory volume in 1 second less than 25% or greater than 80% of predicted normal range, Colonization with Burkholderia cepacia
Required Medical Information	Diagnosis of cystic fibrosis, Positive sputum culture for Pseudomonas aeruginosa, Base line FEV1%. For continuation of therapy the following criteria must be met: Improvement in FEV1% from baseline
Age Restrictions	6 years old and older
Prescriber Restrictions	Pulmonologist and Infectious disease
Coverage Duration	12 months
Other Criteria	Frequency greater than twice daily for 28 days followed by a 28 day drug free period will not be covered

Prior Authorization Group	TRETINOINS
Drug Names	TRETINOIN
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Cosmetic use including wrinkles.
Required Medical Information	The use of topical tretinoin may be considered medically necessary if all of the following criteria are met: Diagnosis of acne vulgaris, Subsequent requests will be considered if there is documentation of: Improvement in acne lesions.
Age Restrictions	10 years old and older
Prescriber Restrictions	-
Coverage Duration	Remainder of contract year
Other Criteria	Failure of a one month trial of each of the following: combination formulary agent containing topical erythromycin and benzoyl peroxide. Combination formulary agent containing topical clindamycin and benzoyl peroxide.

Prior Authorization Group	TRICYCLIC ANTIDEPRESSANTS
Drug Names	AMITRIPTYLINE HCL, AMITRIPTYLINE HYDROCHLORI, DOXEPIN HCL, IMIPRAMINE HCL, IMIPRAMINE HYDROCHLORIDE, TRIMIPRAMINE MALEATE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation of indication of use. The prescriber must be aware that the medication poses a high risk for use in most patients 65 years of age or older. Documentation that the prescriber acknowledges that medication benefit outweigh potential risk in patients 65 years of age or older
Age Restrictions	Prior authorization only applies to patient 65 years or older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	The patient must have a documented failure to one of the following medications for the treatment of depression: Sertraline, Citalopram, Escitalopram, Fluoxetine, Venlafaxine, Duloxetine, or Bupropion. For imipramine used for the treatment of urinary incontinence: if the patient is greater than 18 years of age must have a documented failure of duloxetine if 18 years or less no prior drug failure is required

Prior Authorization Group	TRIENTINE
Drug Names	TRIENTINE HYDROCHLORIDE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Documentation of the diagnosis of Wilson's disease, baseline free serum copper level and 24-hour copper excretion results.
Age Restrictions	6 years and older
Prescriber Restrictions	-
Coverage Duration	Initial 6 month approval, extensions 12 months.
Other Criteria	Must have failed therapy with or have a contraindication to the use of Depen. For continuation of therapy there must be a decrease in free serum cooper level and 24-hour copper excretion results from baseline.

Prior Authorization Group	TYSABRI
Drug Names	TYSABRI
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Patients who have or have had PML. Patients who have had a hypersensitivity reaction to Tysabri. Patients with significantly compromised immune function
Required Medical Information	Multiple Sclerosis: Diagnosis of relapsing-remitting form of multiple sclerosis, neurology notes from the past 2 years and baseline MRI scan prior to initiation of Tysabri. For continuation of therapy-Chart notes identifying continued benefit with a decrease in number of relapses from baseline. Crohn's Disease: Moderate to severe active Crohn's disease confirmed by endoscopy or capsule endoscopy when appropriate. Documentation of active disease such as frequent liquid stools greater than 4 times/day, presence of abdominal pain, presence of abdominal mass, extra-intestinal symptoms, need for opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss greater than 10%. For continuation of therapy-Chart notes identifying response to Tysabri must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms described.
Age Restrictions	18 years old and older
Prescriber Restrictions	Neurologist or gastroenterologist
Coverage Duration	Initial approval 3 months with extensions for 6 months
Other Criteria	Multiple Sclerosis: Documented failure or significant side effects to a trial of two of the following: Avonex, Copaxone or Tecfidera. Documented failure is defined as having two of the following: 1. Two relapses within the previous 12 months 2. MRI identifying lesion progression while on therapy 3. Documented worsening disability while on therapy. Crohn's Disease: Documentation must include failure or inadequate response to a 12-week trial of Humira. OR if chart notes identify intolerance and/or clinical side effects and/or contraindication to Humira, a trial of one corticosteroid and one anti-inflammatory aminosalicylate is required. Tysabri may be covered under Medicare Part B or D depending upon the circumstances. When covered under Part B, Tysabri is not covered under Part D. Information may need to be submitted describing the use and setting of the drug to make the determination.

Prior Authorization Group	UPTRAVI
Drug Names	UPTRAVI
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying:resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients.(Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of therapy is dependent upon documentation of clinical response
Age Restrictions	18 years old and older
Prescriber Restrictions	Pulmonologist or Cardiologist
Coverage Duration	12 months
Other Criteria	Combination therapy with other PAH agents will not be covered for initial therapy
Prior Authorization Group	VALCHLOR
Drug Names	VALCHLOR
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Documentation including workup and skin biopsy results identifying Stage 1A or 1B mycosis fungoides-type cutaneous T-cell lymphoma. Lymph node biopsy if definitive diagnosis cannot be made from skin biopsy. Previous skin-direct therapies
Age Restrictions	18 years old and older
Prescriber Restrictions	Oncologists and Dermatologists
Coverage Duration	Initial 3 month approval, followed by extensions up to 12 months
Other Criteria	Documentation must identify previous treatment with one topical treatment supported by the NCCN Guidelines: Topical corticosteroids, Phototherapy, Topical retinoids, Topical nitrogen mustard or carmustine, Topical imiquimod

Prior Authorization Group	VENTAVIS
Drug Names	VENTAVIS
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying:resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients.(Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of therapy is dependent upon documentation of clinical response
Age Restrictions	18 years old and older
Prescriber Restrictions	Ordered by or Consult with pulmonologist or cardiologist
Coverage Duration	Remainder of contract year
Other Criteria	Combination therapy with other PAH agents will not be covered for initial therapy. Ventavis may be covered under Medicare Part B or D depending upon the circumstances. When covered under Part B, Ventavis is not covered under Part D. Information may need to be submitted describing the use and setting of the drug to make the determination. Coverage will be considered if all of the following criteria are met: NYHA Class III or IV primary pulmonary hypertension or pulmonary hypertension secondary to any of the following conditions: Congenital systemic to vascular shunts, Collagen vascular disease, Portal hypertension, HIV infection, drugs/toxins.
Prior Authorization Group	VRAYLAR
Drug Names	VRAYLAR
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	-
Required Medical Information	Documentation of diagnosis and previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	-
Coverage Duration	12 months
Other Criteria	Must be used for the treatment of schizophrenia or Bipolar I disorder. Must have documentation of failure or significant intolerance to a trial of aripiprazole or quetiapine

Prior Authorization Group	WEIGHT LOSS AGENTS
Drug Names	BELVIQ, CONTRAVE, QSYMIA, SAXENDA, SUPRENZA, XENICAL
Covered Uses	Weight loss after failure of diet and exercise
Exclusion Criteria	Pregnancy, nursing, glaucoma, hyperthyroidism, history of drug abuse, within 14 days of monoamine oxidase inhibitors, combination therapy
Required Medical Information	Documentation of diagnosis, current chart notes and any previous and concurrent therapies
Age Restrictions	Per FDA approved label
Prescriber Restrictions	-
Coverage Duration	1 month initial, then 2-3 month
Other Criteria	BMI 30kg/m ² BMI 27 kg/m ² with at least one of the following: established coronary heart disease (prior myocardial infarction, angina, coronary heart surgery, angioplasty), peripheral artery disease, abdominal aortic aneurysm, symptomatic carotid artery disease), Type 2 diabetes, sleep apnea, hypertension, high LDL cholesterol (160 mg/dL) 27kg/m ² with 3 or more of the following: hypertension, smoker, high LDL cholesterol (130-159 mg/dL), low LDL cholesterol (35mg/dL), impaired fasting glucose (110-125 mg/dL), family history of early cardiovascular disease, age (male 45 yrs, female 55 yrs) prescription history and chart notes must support compliance with diet and exercise and medication use for continuation of therapy continued therapy will be approved if lost at least 4 pounds during initial 1 month of therapy and maintained at least 5% weight loss from baseline Qsymia: failure to achieve 5% weight loss after 12 weeks at maximum dose Saxenda: failure or contraindication to Belviq or Contrave, failure to achieve 4 lb weight loss during initial month or 5% weight loss after 12 weeks of therapy

Prior Authorization Group	XIFAXAN
Drug Names	XIFAXAN
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Will not be covered for prophylactic use or diverticular disease.
Required Medical Information	For diagnosis of active non-invasive travelers diarrhea (TD): Moderate to severe distressing symptoms of travelers diarrhea are present and proven or strongly suspected to be caused by Escherichia coli based upon symptoms and travel destination. (When culture and susceptibility information are available, culture must identify E. coli and susceptible to rifaximin). For diagnosis of hepatic encephalopathy (HE) and Irritable Bowel Syndrome with Diarrhea (IBS-D): current chart notes, current and previous therapies.
Age Restrictions	12 years old and older
Prescriber Restrictions	-
Coverage Duration	TD=3 days, HE=6 months,all other indications=6 months
Other Criteria	The 200mg tablets will only be approved for the treatment of travelers diarrhea at a quantity of 9 tablets. For hepatic encephalopathy must be receiving maximum tolerated dose of lactulose and still having breakthrough overt episodes of hepatic encephalopathy. For Irritable Bowel Syndrome with Diarrhea: must have failed therapy with or have a contraindication to the use of loperamide.

Prior Authorization Group	XOLAIR
Drug Names	XOLAIR
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	For asthma: documented evidence of reversible airway disease, IgE level, test results identifying allergic sensitivity to perennial aeroallergens, previous and current therapy. For Chronic idiopathic urticaria (CIU): Duration of urticaria, previous and current therapy
Age Restrictions	Asthma-6 years and older, CIU-12 years and older
Prescriber Restrictions	-
Coverage Duration	Initial approval-3 months, extensions-12 months
Other Criteria	For asthma: member experiencing poor asthma control despite the use of the maximally tolerated dose of a medium to high dose inhaled corticosteroid in combination with a long-acting beta2 agonist or leukotriene inhibitor or theophylline unless contraindicated, IgE level must be between 30 and 1300 IU/ml. For CIU: Urticaria must be present for at least 6 weeks and other causes such as occupational, food, medication, etc. must have been ruled out, must have failed a minimum of a 2 week trial of the maximally tolerated dose of a potent H1 antihistamine in combination with a H2 antihistamine, a systemic corticosteroid or leukotriene receptor antagonist unless contraindicated

Prior Authorization Group	XYREM
Drug Names	XYREM
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	-
Required Medical Information	The use of Xyrem may be considered medically necessary when the medical information provided documents the following: Definitive diagnosis of narcolepsy based upon objective sleep studies, AND Quantitatively documented symptoms of excessive daytime sleepiness and/or cataplexy, AND no history of GHB abuse, AND no concomitant use with sedative hypnotics (including anxiolytics) or CNS depressants and daily dose does not exceed 9 grams. Continued therapy will be considered based on demonstrated response of decreasing cataplexy events and improvement in score for appropriate test (e.g. Epworth Sleepiness Scale, Clinical Global Impression of Change, etc.) for EDS.
Age Restrictions	18 years old and older
Prescriber Restrictions	-
Coverage Duration	Initial approval: up to 3 months. Continued therapy: 6 months
Other Criteria	Documented intolerance, contraindication, or failure of a 1 month trial of the following: For excessive daytime sleepiness (EDS), modafinil 200mg daily or armodafinil 150mg daily, AND formulary methylphenidate product.

Prior Authorization Group	ZORBTIVE
Drug Names	ZORBTIVE
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Active neoplasia. Acute respiratory failure. Acute critical illness due to complications following open heart or abdominal surgery
Required Medical Information	Documentation that all of the following are met for Short Bowel Syndrome: Surgical resection of small bowel, congenital defect or disease-related loss of absorption. Patient is dependent on parenteral nutritional support and continues to lose weight. Documentation of weight loss or nutritional depletion on current therapies
Age Restrictions	18 years old and older
Prescriber Restrictions	Gastroenterologist
Coverage Duration	4 weeks
Other Criteria	-