

# Medicare Part D Prior Authorization Criteria – Employer-based plan Formulary

Prior Authorization GroupACDrug NamesH.I

Covered Uses
Exclusion Criteria

ACTHAR H.P. ACTHAR

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

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

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Other Criteria For continuation of therapy, documentation must be provided identifying anticipated

length of therapy and improvement in clinical signs and symptoms

Prior Authorization Group

**Drug Names** 

Covered Uses

**Exclusion Criteria** 

Required Medical Information

ACTIMMUNE

ACTIMMUNE

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

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
Other Criteria

3 months initial approval. Remainder of calendar year for extension of therapy

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.

Detween 15-35micron

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

Immunologist. Endocrinologist. Geneticist. Metabolic specialist

12 months

Prior Authorization GroupADCIRCADrug NamesADCIRCA

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

Formulary ID 18473, Version 9 Updated 05/01/2018

Other Criteria

Prior Authorization GroupADEMPASDrug NamesADEMPAS

**Exclusion Criteria** 

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

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 angiograpy 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

Initial 4 months with 12 month extensions

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. Adcirca 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

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

**Prior Authorization Group** 

**Drug Names** 

Covered Uses

**Exclusion Criteria** 

Required Medical Information

**ALDURAZYME ALDURAZYME** 

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

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** 

Other Criteria

6 months

Dose and frequency outside of the FDA approved limits will not be covered

**Prior Authorization Group** 

**Drug Names** Covered Uses

**Exclusion Criteria** 

AI PHA1-ANTITRYPSIN REPLACEMENT THERAPY ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

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

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 IqA, 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

Other Criteria

**Prescriber Restrictions Coverage Duration** 

Must be ordered or followed by a pulmonologist

3 months initial approval. Remainder of contract year for ext of therapy.

Formulary ID 18473, Version 9 Updated 05/01/2018

Prior Authorization Group AMPYRA
Drug Names AMPYRA

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. Approval of Ampyra will be discontinued if the T25FW declines.

Age Restrictions18 years old and olderPrescriber RestrictionsRestricted to neurologists

Coverage Duration Initial: 4 weeks. 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).

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

Other Criteria

Prescriber RestrictionsOncologistCoverage Duration12 months

Prior Authorization Group APTIOM
Drug Names APTIOM

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

Exclusion Criteria Hypersensitivity or severe reaction (ie. Stevens-Johnson Syndrome or drug reaction with

Diagnosis of partial-onset seizures. Prior and current therapies.

eosinophilia and systemic symptoms) to Aptiom OR oxcarbazepine. Severe hepatic

impairment or significant liver injury

Required Medical Information

*Age Restrictions* 18 years of age and older

Prescriber Restrictions

Coverage Duration

Neurologists
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 know 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

Formulary ID 18473, Version 9 Updated 05/01/2018 **Prior Authorization Group ATOVAQUONE Drug Names ATOVAQUONE** 

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

**Exclusion Criteria** 

Required Medical Information Documentation identifies that patient is intolerant to trimethoprim-sulfamethoxazole

> (TMP-SMX), AND one of the following:1. Immunocompromised which requires prevention of Pneumocystis carinii pneumonia (PCP).2. Documented acute

mild-to-moderate PCP.

Age Restrictions 13 years old and older

**Prescriber Restrictions** Restricted to Infectious disease prescriber and oncologists Prevention 12 months. Treatment 21 days

Coverage Duration

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.

18 years and older Age Restrictions

**Prescriber Restrictions** Neurologist **Coverage Duration** 12 months

Other Criteria

### Prior Authorization Group Drug Names

B VS. D

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, ENVARSUS XR, FLUOROURACIL, GANCICLOVIR, GENGRAF, GRANISETRON HCL, HEPATAMINE, INTRALIPID, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE/ALBUT, LEVALBUTEROL, LEVALBUTEROL HCL, 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
Exclusion Criteria
Required Medical Information
Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

NA

NA

Prior Authorization Group

BENLYSTA

BENLYSTA

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** 

Drug Names

**BIOLOGIC RESPONSE MODIFIERS** 

BAVENCIO, FARYDAK, IBRANCE, IDHIFA, IMFINZI, KISQALI, KISQALI FEMARA 200 DOSE, KISQALI FEMARA 400 DOSE, KISQALI FEMARA 600 DOSE, LYNPARZA, MYLOTARG, NINLARO, OPDIVO, RUBRACA, 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

Formulary ID 18473, Version 9 Updated 05/01/2018 Prior Authorization GroupBRIVIACTDrug NamesBRIVIACT

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

**Exclusion Criteria** 

**Required Medical Information** Diagnosis of partial-onset seizures, current antiepileptic drug therapy

Age Restrictions 16 years and older

Prescriber RestrictionsNeurologistCoverage Duration12 months

Other Criteria Must be receiving at least one antiepileptic drug and not be adequately controlled

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

Covered UsesAll FDA-approved indications not otherwise excluded from Part D.Exclusion CriteriaConcomitant 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 soley 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 unale to tolerate the 5mg dose

Prior Authorization Group CICLOPIROX NAIL

**Drug Names** CICLOPIROX NAIL LACQUER

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

Exclusion Criteria

Required Medical Information

Positive KOH test from a nail scraping or a positive pathogenic fungal culture documenting the presence of hyphae consistent with a susceptible dermatophyte (Trichophyton rubrum). No lunula involvement. Member is immunocompromised (e.g.

HIV/AIDS, undergoing chemotherapy, transplant recipient) or has a history of peripheral vascular disease (e.g. diabetes), and/or ADLs are significantly compromised due to the infection. Documented contraindication to terbinafine OR prescription history/chart notes

identify a significant drug interaction with terbinafine.

Age Restrictions 12 years old and older

**Prescriber Restrictions** 

Coverage Duration Remainder of the contract year.

Other Criteria Contraindication or significant drug interaction to/with terbinafine.

Formulary ID 18473, Version 9 Updated 05/01/2018 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 RestrictionsOphthalmologistCoverage Duration12 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 DAKLINZA
Drug Names DAKLINZA

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 18 years old and older

Prescriber Restrictions Infectious disease physician, Gastroenterologist or Hepatologist

Coverage Duration 12 weeks

Other Criteria Must have genotype 1, 2 or 3 disease and be used in combination with sofosbuvir.

Criteria will be applied consistent with current AASLD/IDSA guidance

Prior Authorization GroupDARAPRIMDrug NamesDARAPRIM

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 GroupDIFICIDDrug NamesDIFICID

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 GroupDRONABINOLDrug NamesDRONABINOL

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** 

Drug Names Covered Uses

Exclusion Criteria

Required Medical Information

ENBREL

ENBREL, ENBREL SURECLICK

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

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

Polyarticular juvenile idiopathic arthritis-ages 2 and older, plaque psoriasis-ages 4 and

older. Over 18 years old for all other indications.

Restricted to rheumatologists or immunologists for members with arthropathies,

dermatologists

12 months

Age Restrictions

Prescriber Restrictions

Coverage Duration
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 infdications will be based on significant symptom improvement.

Prior Authorization Group
Drug Names
Covered Uses
Exclusion Criteria
Required Medical Information

EPOETIN EPOGEN, PROCRIT

All medically accepted indications not otherwise excluded from Part D and MDS Uncontrolled hypertension

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)Myleodysplastic 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

restricted to 5 years and older for anemia due to chemo

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

Initial 3 month approval, extensions up to 6 months. Pre-surgical limited to 1 month. 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 GroupFABRY DISEASEDrug NamesFABRAZYME

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

**Exclusion Criteria** The use of Fabrazyme will not be considered medically necessary in the following

situations: members who are carriers of the disease. Doses or frequency exceeding FDA

approved dosing regimen.

**Required Medical Information** Mainz Severity Score Index (MSSI) or FOS Mainz Severity Score Index and/or

globotriaosylceramide level confirming diagnosis. Treatment with Fabrazyme will be considered medically necessary when the following criteria are met: The diagnosis of alpha-galactosidase deficiency is confirmed and supported by at least one of the following. Pain in the extremities, hypohidrosis, corneal opacities, kidney dysfunction, cardiac dysfunction, cerebrovascular disorders. Continued coverage criteria: appropriate

doses and absence of disease progression.

Age Restrictions

Prescriber Restrictions

Coverage Duration

Other Criteria

8 years of age and older

Remainder of the contract year.

**Prior Authorization Group** FENTANYL

Other Criteria

**Drug Names** FENTANYL CITRATE ORAL TRA, FENTORA

Covered UsesAll FDA-approved indications not otherwise excluded from Part D.Exclusion CriteriaIncreased 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 RestrictionsRestricted to oncologists and pain management specialistsCoverage DurationInitial 3 months approval followed by 6 month intervals.

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
Drug Names
Covered Uses
Exclusion Criteria
Required Medical Information

FIRAZYR FIRAZYR

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

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
Prescriber Restrictions
Coverage Duration
Other Criteria

18 years old and older

Allergist, immunologist, or hematologist

Three month intervals

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 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 ostoporotic/fragility fracture despite an adequate trial of oral alendronate of ibandronate. For continued therapy must demonstrate maintenance in BMD of the lumbar spine, femoral neck, or whole body

Age Restrictions Prescriber Restrictions Coverage Duration

Other Criteria

18 years old and older

12 months

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 combinaton with a bisphosphonate. Teriparatide is not covered after two years of treatment.

Prior Authorization Group
Drug Names
Covered Uses

FYCOMPA FYCOMPA

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

Exclusion Criteria
Required Medical Information

Diagnosis of partial-onset seizures or generalized tonic-clonic seizures. Documentation

that Fycompa will be used as adjunctive therapy. Not adequately controlled on a

combination of 2 antiepileptic drugs (AEDs).

Age Restrictions
Prescriber Restrictions

Coverage Duration

Neurologists 12 months

12 years old and older

Other Criteria

Formulary ID 18473, Version 9 Updated 05/01/2018 Prior Authorization Group Drug Names Covered Uses Exclusion Criteria GAUCHERS DISEASE CEREZYME, VPRIV, ZAVESCA

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

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 imiglucerase, velaglucerase alfa, and alglucerase is as follows:diagnosis of Gaucher's Disease Type 1 confirmed by biochemical assay AND member is experiencing symptomatic manifestations of the disease as evidenced by one of the following: 1. documented skeletal disease (osteopenia, avascular osteosclerosis, marrow infiltration, lytic lesions). 2. anemia (Hgb less than or equal to 11.5gm/dL females, Hgb less than or equal to 12.5gm/dL males or 1.0gm/dL below lower limit of normal for age and sex). 3. thrombocytopenia (platelet count less than or equal to 120,000/mm3).4. hepatomegaly or splenomegaly. 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.

Age Restrictions

Imiglucerase is restricted to greater than 2 years old. Miglustat is restricted 18 years and greater. Velaglucerase alfa is restricted to 4 years of age and greater.

Prescriber Restrictions Coverage Duration Other Criteria

Remainder of the contract year.

Prior Authorization GroupGRASTEKDrug NamesGRASTEK

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

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
Other Criteria

**Exclusion Criteria** 

#### 12 months

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** 

**Drug Names Covered Uses Exclusion Criteria**  **GROWTH HORMONE THERAPY** 

HUMATROPE, HUMATROPE COMBO PACK, NORDITROPIN FLEXPRO

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

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/ proliferative or pre-proliferative 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

Prescriber Restrictions

**Coverage Duration** 

Other Criteria

Per package label

**Endocrinologists or Nephrologists** 

12 months

**Prior Authorization Group** 

HEPATITIS C TREATMENT

**Drug Names** EPCLUSA, HARVONI, MAVYRET, VOSEVI, ZEPATIER

Covered Uses **Exclusion Criteria** 

Required Medical Information Documentation of chronic hepatitis C infection, HCV RNA level and genotype,

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

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

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Prior Authorization GroupHEREDITARY ANGIOEDEMADrug NamesCINRYZE, 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-9 years and older, Ruconest-13 years and older

Prescriber RestrictionsAllergist, immunologist or hematologistCoverage Duration6 months initial, extension 12 monthsOther CriteriaDocumentation that triggers of attacks here

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 of 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

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 RestrictionsOncologistCoverage Duration12 months

Other Criteria

Prior Authorization Group Drug Names

HUMIRA

HUMIRA, HUMIRA PEDIATRIC CROHNS D, HUMIRA PEN, HUMIRA PEN-CROHNS

DISEASE, HUMIRA PEN-PSORIASIS STAR

Covered Uses
Exclusion Criteria
Required Medical Information

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

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

Restricted to 18 years of age and older, except for JIA which is restricted to 2 years and

older and Crohn's which is 6 and older

**Prescriber Restrictions** 

Restricted to rheumatologists or immunologists for members with arthropathies, dermatologists, gastroenterologists, colorectal surgeons, ophthalmologist 12 months

Coverage Duration
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** 

**Drug Names** 

Covered Uses

**Exclusion Criteria** 

Required Medical Information

ILARIS ILARIS

All FDA-approved indications not otherwise excluded from Part D

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):

 $\label{lem:composition} \mbox{Documented disease activity for 6 months, Chart notes identifying synovitis and number}$ 

of swollen and/or tender joints

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

Rheumatologist, immunologist or dermatologist Initial 4 months with 12 month extensions

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

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

### Prior Authorization Group Drug Names

#### Covered Uses

## Exclusion Criteria Required Medical Information

### IMMUNOGLOBULIN THERAPY

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

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 cytomeglovirus (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.

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 with

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

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

Covered Uses
Exclusion Criteria
Required Medical Information

INTRAVENOUS (IV) VS. ORAL CIPROFLOXACIN I.V.-IN D5W, GRANISETRON HCL, LEVOFLOXACIN, LEVOFLOXACIN IN D5W, LINEZOLID, ONDANSETRON HCL

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

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.

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

Restricted to FDA approved package labeling age restrictions.

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 GroupITRACONAZOLEDrug NamesITRACONAZOLE

Covered Uses All FDA-approved indications not otherwise excluded from Part D and the following: tinea

corporis, cruris or pedis Congestive heart failure

18 years old and older

**Required Medical Information** MEDICAL INFO: 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 following1.

Blastomycosis. 2. Histoplasmosis. 3. Aspergillosis.

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

**Exclusion Criteria** 

Onychomycosis-12 weeks, all other indications-12 months

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** 

Required Medical Information

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

**Exclusion Criteria** Chronic myelogenous leukemia, myelodysplastic syndrome, or other myeloid neoplasm.

> Documentation provided supporting the diagnosis of intermediate-2 (2 prognostic factors) or high-risk (3 or more prognostic factors) 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: documentation provided must identify a 35 percent reduction in spleen size and decrease in symptoms vs baseline MFSAF total symptom score. For Polycythemia vera: hemoglobin greater than 18.5 g/dL in men or 16.5 g/dL in women and presence of JAK2617V or other functionally similar mutation. For continuation of therapy must have absence of

phlebotomy and spleen volume reduction of 35%

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 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 Restrictions2 years and olderPrescriber RestrictionsPulmonologistCoverage Duration6 months

Other Criteria More than 60 tablets per 30 days are not covered. Kalydeco is not effective in patients

with CF who are homozygous for the F508del mutation in the CFTR gene.

Prior Authorization Group

**Drug Names** 

KINASE INHIBITORS

AFINITOR, AFINITOR DISPERZ, ALECENSA, ALIQOPA, ALUNBRIG, BOSULIF, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COTELLIC, ICLUSIG,

IMATINIB MESYLATE, IMBRUVICA, INLYTA, IRESSA, LENVIMA 10 MG DAILY DOSE, LENVIMA 14 MG DAILY DOSE, LENVIMA 18 MG DAILY DOSE, LENVIMA 20 MG DAILY DOSE, LENVIMA 24 MG DAILY DOSE, LENVIMA 8 MG DAILY DOSE, MEKINIST, NERLYNX, NEXAVAR, RYDAPT, SPRYCEL, STIVARGA, SUTENT,

TAGRISSO, XALKORI, 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
Coverage Duration

Other Criteria

Oncologist 12 months

Formulary ID 18473, Version 9 Updated 05/01/2018 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 Restrictions18 years and olderPrescriber RestrictionsEndocrinologist

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
Coverage Duration
Other Criteria

Specialist or prescriber with experience in PKU 2 months initial approval, extension 6 months

Prior Authorization GroupKYNAMRODrug NamesKYNAMRO

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

Diagnosis of homozygous familial hypercholosterologia. Paseline ALT, AST, alkaline

**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 equanalgesic 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

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.

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 6

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.

required medical information Documentation of diagnosis of post-nerpetic neuralgia of diabetic neuropating

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

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

Other Criteria

12 months

**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** 

**Drug Names** 

**Covered Uses** 

**Exclusion Criteria** 

Required Medical Information

Age Restrictions **Prescriber Restrictions** 

Other Criteria

**Coverage Duration** 

**MODAFINIL MODAFINIL** 

All medically accepted indications not otherwise excluded from Part D

Condition modafinil 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

17 years old and older

12 months

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 Medicar Prescription Drug Benefit

Manual

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
Other Criteria

Initial approval 6 months, extensions 12 months

To be eligible for approval of Myalept therapy the patient must NOT have any of the following: Partial lipodystrophy, HIV-related lipodystropy, 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

Other Criteria

Initial approval 6 months, extensions 12 months

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 Patient must be unable to maintain a corrected serum calcium of 8.5mg/dL greater . 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 GroupNUPLAZIDDrug NamesNUPLAZID

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 GroupODOMZODrug NamesODOMZO

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 RestrictionsOncologistCoverage Duration12 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 GroupOPSUMITDrug NamesOPSUMIT

Covered Uses All FDA-approved 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 angiograpy 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 Restrictions18 years old and olderPrescriber Restrictionscardiologist 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 12 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
Drug Names
Covered Uses
Exclusion Criteria
Required Medical Information

PRALUENT PRALUENT

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

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

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

18 years old and older

## 12 months

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 GroupPROMACTADrug NamesPROMACTACovered UsesAll 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 x 10 to the 9th/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 x 109/L. Outcomes of any previous therapies such as splenic artery embolization, splenectomy or TIPS.

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

6 years old and older Hematologist and hepatologist

Initial approval will be for 3 months. Extension of therapy up to one year.

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, 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 400x 10 to the 9th/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 that 50 x 10 to the 9th/L. Platelet cout must increase after 4 weeks at the maximum dose. For chronic hepatitis C to allow initiation an maintenance of interferon-based therapy: Requires adequate response with a platelet count of greater than 90 x 10 to the 9th/L. Platelet count must increase after 2 weeks at the maximum FDA approved dose. Severe Aplastic Anemia: platelet count must increase to 20 x 10 to the 9th/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 0.5x10 to the 9th/L after 12 weeks of therapy

Prior Authorization GroupRAGWITEKDrug NamesRAGWITEK

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

Exclusion Criteria Severe, unstable or uncontrolled asthma. History of esinophilic 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

Age Restrictions 18 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 (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 Drug Names Covered Uses Exclusion Criteria** 

**REMICADE REMICADE** 

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

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. 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.

Restricted to 18 years of age and older, except for Crohn's and ulcerative colitis which is restricted to 6 years and older.

Restricted to rheumatologists, immunologists, dermatologists, gastroenterologists, colorectal surgeons

Initial approval for 3 months with extensions of up to 6 months intervals

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.

## Required Medical Information

Age Restrictions

Prescriber Restrictions

**Coverage Duration** Other Criteria

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.Plague 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 RIBAVIRIN

**Drug Names** RIBASPHERE, RIBAVIRIN

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

**Exclusion Criteria** Contraindications for the use of ribavirin, including pregnancy, renal failure,

hemoglobinopathies.

Required Medical Information

Age Restrictions

**Prescriber Restrictions** 

Coverage Duration

Other Criteria

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 GroupSILDENAFILDrug NamesSILDENAFIL

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 therpay.

**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 GroupSOVALDIDrug NamesSOVALDI

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

**Exclusion Criteria** 

**Required Medical Information** HCV RNA level and genotype. Patients with hepatocellular carcinoma awaiting liver

transplantation: Member meets Milan criteria and will be receiving transplant within 48

week

Age Restrictions 12 years old and older

Prescriber Restrictions Infectious disease physician, Gastroenterologist or Hepatologist

Coverage Duration 12 to 48 weeks based on indication

Other Criteria Will be applied consistent with current AASLD/IDSA guidance

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 Restrictions18 years old and olderPrescriber RestrictionsOncologist 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** SYPRINE

**Drug Names** SYPRINE, 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 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 Restrictions18 years old and olderPrescriber RestrictionsRestricted 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 GroupTOBI PODHALERDrug NamesTOBI 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 tretinoins 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
Prescriber Restrictions
Coverage Duration

Remainder of contract year

10 years old and older

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** 

Drug Names
Covered Uses
Exclusion Criteria

TRICYCLIC ANTIDEPRESSANTS

AMITRIPTYLINE HCL, DOXEPIN HCL, IMIPRAMINE HCL, TRIMIPRAMINE MALEATE

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

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
Prescriber Restrictions
Coverage Duration
Other Criteria

Prior authorization only applies to patient 65 years or older

12 months

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 TYSABRI
Drug Names TYSABRI

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

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
Prescriber Restrictions
Coverage Duration
Other Criteria

**Exclusion Criteria** 

Neurologist or gastroenterologist

18 years old and older

Initial approval 3 months with extensions for 6 months

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 aripirazole or quetiapine

**Prior Authorization Group** 

Drug Names
Covered Uses
Exclusion Criteria

WEIGHT LOSS AGENTS

BELVIQ, CONTRAVE, QSYMIA, SAXENDA, SUPRENZA, XENICAL

Weight loss after failure of diet and excercise

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
Prescriber Restrictions

Coverage Duration
Other Criteria

Per FDA approved label

1 month initial, then 2-3 month

BMI 30kg/m2 BMI 27 kg/m2 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/m2 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 Osymia: 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

Required Medical Information

Covered UsesAll FDA-approved indications not otherwise excluded from Part D.Exclusion CriteriaWill not be covered for prophylactic use or diverticular disease.

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
Prescriber Restrictions
Coverage Duration
Other Criteria

12 years old and older

TD=3 days, HE=6 months, all other indications=6 months

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 GroupXOLAIRDrug NamesXOLAIR

Covered Uses
Exclusion Criteria

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

Required Medical Information

For asthma: documented evidence of reversible airway disease, IgE level, test results identifying allergic sensitivity to perennial aeroallergens, previosu and current therapy. For Chronic idiopathic urticaria (CIU): Duration of urticaria, previous and current therapy Asthma-6 years and older, CIU-12 years and older

Age Restrictions
Prescriber Restrictions
Coverage Duration

Other Criteria

Initial approval-3 months, extensions-12 months

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 agoinst or leukotriene inhibitor or theophylline unless contraindicated, IgE level must be between 30 and 700 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 anxioloytics) 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 Other Criteria

Initial approval: up to 3 months. Continued therapy: 6 months

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 GroupZORBTIVEDrug NamesZORBTIVE

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
Prescriber Restrictions
Coverage Duration
Other Criteria

18 years old and older Gastroenterologist

4 weeks