

## Medicare Part D drugs that require prior authorization

## PA Criteria

Prior Authorization Group ACTIMMUNE
Drug Names ACTIMMUNE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses
Exclusion Criteria

Required Medical Information

Supporting documentation including prescription history with intravenous antibiotics, complete blood count (CBC) with differential identifying anemia or thrombocytopenia. Documented diagnosis of Chronic Granulomatous Disease (CGD) and continued frequent serious infectious episodes while receiving prophylactic antibiotics, OR Diagnosis of severe, malignant osteopetrosis supported by radiological reports, documentation of previous therapy with intravenous antibiotics, and other relevant clinical findings that were used to diagnosis osteopetrosis and which will be monitored for outcomes such as: anemia, thrombocytopenia, splenomegaly, optic atrophy, chronic osteomyelitis. Continued therapy will be considered based on demonstrated response identified by reduction in serious infections requiring intravenous antibiotics (CGD), reduction in hospitalizations due to serious infections (CGD), increase in hemoglobin and platelet counts (osteopetrosis), no more than 50dB decrease in hearing and no evidence of progressive optic atrophy (osteopetrosis), no evidence of a serious bacterial infection requiring antibiotics (osteopetrosis).

Age Restrictions
Prescriber Restrictions

Hematologist. Oncologist. Endocrinologist. Infectious Disease specialist. Orthopedist.

Rheumatologist

Coverage Duration
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 ADEMPAS
Drug Names ADEMPAS

PA Indication Indicator All Medically-accepted Indications

Off-label Uses

**Exclusion Criteria**Coverage will not be provided if any of the following are true: Use in pregnancy, Coadministration of Adempas with a phosphodiesterase inhibitor, including specific PDE-5 inhibitors (i.e. sildenafil, tadalafil, vardenafil), nonspecific PDE inhibitors (i.e.

theophylline or dipyridamole), nitrates or nitric oxide donors. Presence of pulmonary

veno-occlusive disease

Required Medical Information

If WHO Group I verification of pulmonary hypertension due to idiopathic (IPAH), familial (FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying: resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg.. If WHO Group 4, verification of CTEPH diagnosis via ventilation-perfusion scanning and confirmatory pulmonary angiography AND Documentation of persistence/recurrence of CTEPH following surgical treatment OR Documentation that indicates patient is not considered a surgical candidate for the treatment of CTEPH. If WHO Group 1, vasoreactive testing is recommended for all PAH patients (documentation with rationale must be provided for patients for whom this testing is not performed). Documentation of previous and current therapies identifying outcome. Extension of therapy will be dependent upon documentation of clinical response and lack of deterioration

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

18 years old and older

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. tadalafil or sildenafil) or Endothelin receptor antagonist-ambrisentan or Opsumit. Combination therapy with other PAH agents will not be covered for initial therapy. Doses greater than the FDA approved maximum dose will not be covered

Prior Authorization Group Drug Names PA Indication Indicator Off-label Uses

ALPHA1-ANTITRYPSIN REPLACEMENT THERAPY ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

All Medically-accepted Indications

Exclusion Criteria

Not covered if any of the following situations are true: 1. PiMZ or PiMS phenotypes 2. Members identified with selective IgA deficiencies (IgA level less than 15mg per dl) who have known antibodies against IgA, since they may experience severe reactions 3. Dosing exceeding package labeling 4.Frequency exceeding once weekly infusions 5. Coverage is not provided for doses exceeding package labeling. 6. Emphysema not due to AAT deficiency.

Required Medical Information

Progressive clinically evident emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV1) post bronchodilation between 30 and 65% predicted except when: 1. Nearly normal pulmonary function if they experience a rapid decline in lung function (FEV1 greater than 120 ml/yr) OR 2. Poor lung function and currently receiving standard treatment. AAT serum level less than 11 micrometer or less than 80mg per dL., rate of decline in forced expiratory volume in 1 second (FEV1) post bronchodilation between 30 and 65% predicted, Phenotype is identified as PiZZ, PiZ(null) or Pi(null)(null). Continued therapy will be considered based on demonstrated response in slowing progression of lung function decline

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

Must be ordered or followed by a pulmonologist

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

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Prior Authorization Group AMBRISENTAN Drug Names AMBRISENTAN

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Coverage will not be provided for: more than 1 tablet per day, or for the treatment of

digital ulcers or erectile dysfunction.

**Required Medical Information** Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial

(FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying: resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients.(Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of

therapy is dependent upon documentation of clinical response

Age Restrictions 18 years old and older

Prescriber Restrictions Ordered by or Consult with pulmonologist or cardiologist

Coverage Duration Initial authorization will be limited to 3 months. Extended authorizations limited to 12

months

Other Criteria -

**Prior Authorization Group** ANTIMETABOLITES

**Drug Names**INQOVI, LONSURF, ONUREG **PA Indication Indicator**All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Diagnosis for the requested drug, with current clinical documentation of any previous

therapies tried.

Age Restrictions -

Prescriber Restrictions Oncologist
Coverage Duration 12 months

Other Criteria -

ARCALYST - PENDING CMS REVIEW **Prior Authorization Group** 

**ARCALYST Drug Names** 

**PA Indication Indicator** 

Off-label Uses

**Exclusion Criteria** 

**Required Medical Information** 

**Age Restrictions** 

**Prescriber Restrictions Coverage Duration** 

Other Criteria

**Prior Authorization Group AURYXIA AURYXIA Drug Names** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses

**Exclusion Criteria** For the treatment of iron deficiency anemia in adult patients with chronic kidney

Current clinical documentation indicating the use for Auryxia

disease not on dialysis. Prescription medications used as vitamin or mineral products, are excluded from Medicare Part D coverage. Auryxia is considered a vitamin or mineral product when used for the treatment of iron deficiency anemia. For the

treatment of hyperphosphatemia in adult patients with chronic kidney disease NOT on

dialysis

**Required Medical Information** 

Age Restrictions

**Prescriber Restrictions** 

Ordered by or Consult with nephrologist

**Coverage Duration** 12 months

Other Criteria

## Prior Authorization Group Drug Names

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ABELCET, ACETYLCYSTEINE, ACYCLOVIR SODIUM, ALBUTEROL SULFATE, AMPHOTERICIN B, APREPITANT, ARFORMOTEROL TARTRATE, AZATHIOPRINE, BLEOMYCIN SULFATE, BUDESONIDE, CINACALCET HYDROCHLORIDE, CROMOLYN SODIUM, CYCLOPHOSPHAMIDE, CYCLOSPORINE, CYCLOSPORINE MODIFIED, CYTARABINE, CYTARABINE AQUEOUS, ENGERIX-B, EVEROLIMUS, FLUOROURACIL, FORMOTEROL FUMARATE, GENGRAF, GRANISETRON HYDROCHLORIDE, INTRALIPID, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE/ALBUT, LEVALBUTEROL, LEVALBUTEROL HCL, MYCOPHENOLATE MOFETIL, MYCOPHENOLIC ACID DR, NULOJIX, ONDANSETRON HCL, ONDANSETRON HYDROCHLORIDE, ONDANSETRON ODT, PENTAMIDINE ISETHIONATE, PREHEVBRIO, PREMASOL, PROCRIT, PROGRAF, PROSOL, PULMOZYME, RECOMBIVAX HB, RETACRIT, SIMULECT, SIROLIMUS, TACROLIMUS, THYMOGLOBULIN, TOBRAMYCIN, TOBRAMYCIN SULFATE, TRAVASOL, TROPHAMINE, VARUBI, YUPELRI

PA Indication Indicator

All Medically-accepted Indications

Off-label Uses Exclusion Criteria Required Medical Information Age Restrictions Prescriber Restrictions Coverage Duration NA

Prior Authorization Group

BENLYSTA

BENLYSTA

BENLYSTA

PA Indication Indicator

All Medically-accepted Indications

Off-label Uses -

**Required Medical Information** 

**Exclusion Criteria**Benlysta has not been evaluated and is not recommended in patients with severe

active central nervous system lupus or in combination with other biologic products.

Patient has a 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. 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)

Patient has active lupus nephritis, and Benlysta will be used in combination with standard therapy including, but not limited to, corticosteroids, cyclosporine, tacrolimus,

cyclophosphamide, azathioprine, mycophenolate.

Age Restrictions

Prescriber RestrictionsRheumatologist, nephrologistCoverage Duration6 months initial, extension 12 months

Other Criteria Documentation of response to Benlysta must be provided with each request for

extension of therapy that identifies improvement in the clinical signs and symptoms of

the disease state.

**Prior Authorization Group** 

**Drug Names** 

**BIOLOGIC RESPONSE MODIFIERS** 

DAURISMO, FARYDAK, IBRANCE, IDHIFA, KISQALI, KISQALI FEMARA 200 DOSE, KISQALI FEMARA 400 DOSE, KISQALI FEMARA 600 DOSE, LYNPARZA, NINLARO, RUBRACA, TALZENNA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, XPOVIO, XPOVIO 60 MG TWICE WEEKLY, XPOVIO 80 MG TWICE WEEKLY,

ZEJULA. ZYDELIG

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Diagnosis for the requested drug, with current clinical documentation of any previous

therapies tried.

Age Restrictions -

Prescriber RestrictionsOncologistCoverage Duration12 months

Other Criteria -

Prior Authorization GroupCAYSTONDrug NamesCAYSTON

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Known allergy to aztreonam

**Required Medical Information** Diagnosis of cystic fibrosis and sputum culture positive for Pseudomonas aeruginosa,

FEV1 results

Age Restrictions -

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** CGRP ANTAGONISTS

**Drug Names**AIMOVIG, AJOVY, EMGALITY **PA Indication Indicator**All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** 

For the preventative treatment of migraines, the requested drug will be covered when the following criteria are met: the patient has experienced an inadequate treatment response, intolerance, or contraindication to, a 4 week trial with ANY of the following preventative drug classes: anti-epileptic drugs, beta-adrenergic blockers, antidepressants, OR the patient has received at least 3 months of treatment with the requested drug, and had a reduction in migraine days per month from baseline. For episodic cluster headache (Emgality only), the request indicates the patient has experienced an inadequate treatment response, or intolerance to, a 4-week trial of one medication class supported in the compendia for preventative treatment, such as

verapamil.

\*\*Age Restrictions\*\* -

Prescriber Restrictions
Coverage Duration

Other Criteria

Initial approval 3 months, continuation 12 months.

For continued therapy: physician attestation must be provided with each extension request indicating a reduction in migraine/headache days per month from baseline, or

an improvement in the patient's overall condition.

Prior Authorization Group Drug Names PA Indication Indicator Off-label Uses Exclusion Criteria CORTICOTROPIN
ACTHAR, CORTROPHIN
All Medically-accepted Indications

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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 corticotropin 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 corticotropin

**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, dimethyl fumarate, 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, juvenile rheumatoid arthritis/juvenile idiopathic 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, serum sickness, 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
Other Criteria

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3 months

Infantile Spams: must be less than 2 years of age. For continuation of therapy, documentation must be provided identifying anticipated length of therapy and improvement in clinical signs and symptoms

**Prior Authorization Group** CYSTARAN

**Drug Names**CYSTADROPS, CYSTARAN **PA Indication Indicator**All Medically-accepted Indications

Off-label Uses -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 DIACOMIT Drug Names DIACOMIT

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** There is no clinical data to support the use of Diacomit as monotherapy in Dravet

syndrome. Diacomit as monotherapy is not covered.

**Required Medical Information** Prescriber attests that Diacomit will be used for the treatment of seizures associated

with Dravet syndrome, and clobazam is currently, or will be used, in conjunction.

Coverage Duration 12 months

Other Criteria -

Prior Authorization GroupDIFICIDDrug NamesDIFICID

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Stool sample positive for clostridium difficile toxin.

Age Restrictions -

**Prescriber Restrictions** Restricted to Infectious Disease and gastroenterologist.

Coverage Duration 10 days

Other Criteria Failure of a 10-14 day course of treatment of oral vancomycin. (Recurrence of c.

difficile AFTER treatment with vancomycin does not meet the criteria for failure of

vancomycin.)

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**Prior Authorization Group** DRIZALMA

**Drug Names** DRIZALMA SPRINKLE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation indicating the patient has tried duloxetine capsules or the patient is

unable to take duloxetine capsules for any reason (e.g., difficulty swallowing capsules.

requires nasogastric administration)

Age Restrictions -

Prescriber Restrictions -

Coverage Duration 12 months

Other Criteria -

Prior Authorization GroupDRONABINOLDrug NamesDRONABINOL

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

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 GroupDUPIXENTDrug NamesDUPIXENT

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Dosing that exceeds FDA-approved labeling for the indication will not be a covered

benefit.

**Required Medical Information** For Atopic Dermatitis: documentation indicates moderate-to-severe atopic dermatitis.

The patient must have an inadequate response to ONE of the following: topical corticosteroids, topical calcineurin inhibitors (tacrolimus ointment, pimecrolimus cream), Eucrisa. For moderate to severe asthma: documentation indicates the patient has eosinophilic phenotype moderate-to-severe asthma, or oral corticosteroid-dependent moderate to severe asthma, with continued exacerbations despite compliant use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta2-agonist (LABA). For add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRwNP): documentation indicates the disease is inadequately controlled with current therapy,

such as nasal steroids.

Age Restrictions

**Prescriber Restrictions**Must be prescribed by or in consultation with a dermatologist, immunologist,

gastroenterologist, pulmonologist, otolaryngologist.

Coverage Duration Initial approval-3 months, extensions-12 months

Other Criteria For continued therapy: Documentation of response must be provided with each request

for extension of therapy that identifies improvement in the clinical signs and symptoms

of the disease state.

Prior Authorization Group EGRIFTA

**Drug Names** EGRIFTA SV

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Egrifta is not indicated for cosmetic use or weight loss management. There are no data

to support improved compliance with anti-retroviral therapies in HIV-positive patients

taking Egrifta.

**Required Medical Information** Documentation indicating that Egrifta will be used for the treatment of excess

abdominal fat in patients with HIV-associated lipodystrophy.

Age Restrictions 18 to 65 years of age

Prescriber Restrictions -

Coverage Duration 6 months

Other Criteria For continued therapy: Documentation of response identifies improvement in the

clinical signs and symptoms. Examples include improvement in visceral adipose tissue

[VAT], decrease in waist circumference, belly appearance.

**Prior Authorization Group** ENBREL

**Drug Names** ENBREL, ENBREL MINI, ENBREL SURECLICK

PA Indication Indicator All Medically-accepted Indications

Off-label Uses
Exclusion Criteria

Required Medical Information

A. For moderate to severe active adult RA the following must be met: Failed to respond to 1 or more nonbiologic DMARDs, one of which is a trial of a maximally tolerated dose of methotrexate. If the member has a contraindication or significant intolerance to methotrexate, the member must have failed to respond to a trial of 1 other DMARD at a maximally tolerated dose. B. For moderate to severe JIA as indicated by 4 affected ioints with limitation of motion, pain, tenderness or both, or persistent symptoms, the following criteria must be met: Failure to respond to at least a 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 a trial of at least 1 DMARD. D. Enbrel for plague 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. A 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.

Age Restrictions

Polyarticular juvenile idiopathic arthritis-ages 2 and older, plaque psoriasis-ages 4 and older. Over 18 years old for all other indications.

Prescriber Restrictions

Restricted to rheumatologists or immunologists for members with arthropathies,

dermatologists

**Coverage Duration** 

12 months

Other Criteria

For continued therapy: documentation of response (ie, stable condition) to Enbrel must

be provided with each request.

Prior Authorization GroupENSPRYNGDrug NamesENSPRYNG

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Patients with an active Hepatitis B infection, or have active, or latent tuberculosis **Required Medical Information** Request must indicate the patient has neuromyelitis optica spectrum disorder

(NMOSD) and are anti-aquaporin-4 (AQP4) antibody positive.

Age Restrictions -

Prescriber Restrictions
Coverage Duration
Other Criteria

Must be prescribed by, or in consult with, a neurologist or ophthalmologist

Initial approval-6 months. Extensions thereafter-12 months

For continued therapy: Documentation of response must be provided with each request for extension of therapy that identifies improvement, or stability in the clinical signs and

symptoms of NMOSD.

Prior Authorization GroupEPIDIOLEXDrug NamesEPIDIOLEX

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Request is for an FDA approved indication, or an indication supported in the CMS

recognized compendia

Age Restrictions -

**Prescriber Restrictions** Prescribed by, or in consult with a neurologist

Coverage Duration 12 months

Other Criteria -

**Prior Authorization Group** ESBRIET

**Drug Names** ESBRIET, PIRFENIDONE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - 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 For continuation of therapy, the documentation must identify an improvement or

maintenance of disease.

Prior Authorization GroupEVRYSDIDrug NamesEVRYSDI

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Concomitant therapy with other treatments for spinal muscular atrophy (SMA)

**Required Medical Information** The patient must be diagnosed with Type 1, 2, or 3 spinal muscular atrophy, evidenced

by supporting diagnostic genetic tests confirming 0 copies of SMN1, 2 copies of SMN2, OR genetic testing of 5q SMA for any of the following: homozygous gene deletion, homozygous conversion mutation, or compound heterozygote. The patient must have documentation of SMA-associated signs and symptoms and does not require invasive

ventilation or a tracheostomy due to advanced SMA disease.

Age Restrictions

**Prescriber Restrictions**Must be prescribed by a neurologist or geneticist

Coverage Duration 6 months

Other Criteria For continued therapy: documentation of clinically significant improvement in spinal

muscular atrophy-associated signs and symptoms (such as progression, stabilization, or decreased decline in motor function) compared to baseline. Doses exceeding 5mg

per day are not a covered benefit.

Prior Authorization Group FABRY DISEASE
Drug Names GALAFOLD

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** For Galafold, uncertain clinical significance of variant status should be determined by a

genetics professional. Doses or frequency exceeding FDA approved dosing regimen.

**Required Medical Information** Treatment with Galafold will be considered medically necessary when the following

criteria are met: a. Diagnosis of Fabry disease b. Patient has an amenable

galactosidase alpha gene (GLA) variant based on in vitro assay data. For continued

coverage: Documentation of positive clinical response to therapy.

Age Restrictions -

Prescriber Restrictions -

**Coverage Duration** Remainder of the contract year.

Other Criteria -

**Prior Authorization Group** FASENRA

**Drug Names** FASENRA, FASENRA PEN

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria**Dosing that exceeds FDA-approved labeling for the indication will not be a covered

benefit.

**Required Medical Information** As add on maintenance therapy for severe asthma: documentation indicates the patient

has eosinophilic phenotype severe asthma, with continued exacerbations, requiring oral systemic corticosteroids, despite the use of a high-dose inhaled corticosteroid

(ICS) and a long-acting beta2-agonist (LABA).

Age Restrictions

**Prescriber Restrictions** 

Coverage Duration
Other Criteria

Must be prescribed by, or in consultation with, an immunologist or pulmonologist

Initial approval-3 months, extensions-12 months

For continued therapy: Documentation of response must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms

of the disease state.

**FENTANYL** 

**Prior Authorization Group** 

**Drug Names** 

FENTANYL CITRATE, FENTANYL CITRATE ORAL TRA

PA Indication Indicator

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Off-label Uses
Exclusion Criteria

All Medically-accepted Indications

Increased strength and/or frequency other than approved dosing are excluded.

Treatment of acute or postoperative pain. Combination use of short-acting fentanyl

products. Monotherapy.

**Required Medical Information** Diagnosis of cancer. Documentation indicates that use is for breakthrough cancer pain.

For extension of therapy, documentation must identify 1.continued benefit from therapy,

and 2.dosing of long-acting product has been evaluated and is at the maximum

tolerated dose.

Age Restrictions Transmucosal solid dosage form restricted to 16 and older. All other forms restricted to

18 years and older.

Prescriber Restrictions
Coverage Duration

Other Criteria

Restricted to oncologists and pain management specialists Initial 3 months approval followed by 6 month intervals.

Fentanyl oral transmucosal or buccal solid dosage forms require prior authorization (for

all quantities) and will be considered medically necessary when all of the following criteria are met: 1. Failure of a trial of at least 2 different immediate-release (short-

acting) opioid drugs at the maximum tolerated dose are ineffective to control

breakthrough pain. 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 GroupFIRDAPSEDrug NamesFIRDAPSE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Patients with a history of seizures or seizure disorder.

**Required Medical Information** 1. Diagnosis of LEMS 2. Documentation of a baseline clinical muscle strength

assessment (examples may include but are not limited to, a Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test

(T25FW)).

Age Restrictions 18 years and older

Prescriber Restrictions Prescribed by or in consultation with a neurologist

Coverage Duration Initial coverage: 6 months Continued coverage: 12 months

Other Criteria Continuation of therapy will be based on a documented positive response evidenced by

an updated stable or improved clinical muscle strength assessment. Examples may include but are not limited to, a Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW). Non-FDA approved diagnoses will be evaluated according to the CMS medically accepted indications requirements in Chapter 6 of the Medicare Prescription Drug Benefit Manual.

**Prior Authorization Group** 

**Drug Names** 

PA Indication Indicator

Off-label Uses
Exclusion Criteria

Required Medical Information

**FORTEO** 

FORTEO, TERIPARATIDE

All Medically-accepted Indications

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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 oral alendronate, or

ibandronate unless the member has a contraindication or intolerance to bisphosphonates: or 2. New osteoporotic/fragility fracture despite treatment with oral

alendronate or risedronate. For continued therapy must demonstrate maintenance in

BMD of the lumbar spine, femoral neck, or whole body

Age Restrictions 18 years old and older Prescriber Restrictions -

Coverage Duration
Other Criteria

24 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 combination with a bisphosphonate. The use of teriparatide for more than 2 years during a patient's lifetime should only be considered if a patient remains at, or has returned to having a high risk for fracture.

Formulary IDs 23177 and 23180, Version 2 Updated 01/01/2023

**Prior Authorization Group** 

**Drug Names** 

**MIGLUSTAT** PA Indication Indicator

Off-label Uses

All Medically-accepted Indications

**GAUCHERS DISEASE** 

**Exclusion Criteria** 

The use of these agents will not be considered medically necessary in the following

situations: members with Type 2 or Type 3 Gaucher's Disease. asymptomatic Type 1 disease. carriers of Gaucher's Disease. combination use of any of these agents. Miglustat is not covered for severe disease (severe disease defined as a hemoglobin concentration below 9 g/dL or a platelet count below 50 x 10 to the 9th/L or active bone disease). Miglustat is not covered for diagnosis other than Type 1 Gaucher Disease. Miglustat is not covered if there is no documented allergy, hypersensitivity, or poor venous access to enzyme replacement therapy. These agents are not covered for any

diagnosis other than Gaucher's disease.

**Required Medical Information** 

Medical information required for miglustat is as follows: diagnosis of Gaucher's Disease Type 1 confirmed by biochemical assay AND member is experiencing symptomatic manifestations of the disease AND member has a contraindication for use of enzyme replacement therapy such as allergy, hypersensitivity reaction or poor venous access. Miglustat is restricted 18 years and greater.

**Age Restrictions Prescriber Restrictions** 

**Coverage Duration** 

Remainder of the contract year.

Other Criteria

**Prior Authorization Group GRASTEK GRASTEK Drug Names** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses **Exclusion Criteria** 

**Required Medical Information** 

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. Will not be covered if receiving subcutaneous allergen immunotherapy Patient has documented allergic rhinitis with or without conjunctivitis. Hypersensitivity to Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard, Perennial Rye, Kentucky Blue Grass, Meadow Fescue, and Redtop) should be confirmed by positive skin test or in vitro testing for pollen specific laE antibodies prior to administration. Documentation must identify failure of at least TWO of the following treatments: an intranasal corticosteroid, oral antihistamine, or an oral leukotriene receptor antagonist.

Age Restrictions **Prescriber Restrictions Coverage Duration** Other Criteria

Ages 5 through 65 years of age

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. For continuation of treatment, the benefits of treatment (decrease of symptoms, increase tolerance to grass pollen) must be documented. 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.

**Prior Authorization Group** 

**Drug Names** 

**GROWTH HORMONE THERAPY** HUMATROPE, NORDITROPIN FLEXPRO

PA Indication Indicator

Off-label Uses

**Exclusion Criteria** 

All Medically-accepted Indications

patient is in a non-euthyroid state. If GHD results from an intracranial tumor, absence of tumor growth or tumor recurrence for at least 6 months prior to therapy initiation. GH is not indicated for treatment of wounds or burns. PWS with 1 or more risk factors including severe obesity, h/o respiratory impairment or sleep apnea, or unidentified respiratory infection. Catabolic illnesses or to improve muscle strength or exercise tolerability. Members w/ active proliferative or severe non-proliferative (preproliferative) diabetic retinopathy. Extension of therapy for children for GHD will not be covered if

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

GH will not be covered for the following: patient has an active malignant condition,

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** 

**Endocrinologists or Nephrologists** 

**Coverage Duration** 

12 months

Per package label

Other Criteria

**Prior Authorization Group** 

**Drug Names** 

EPCLUSA, HARVONI, MAVYRET, SOVALDI, VOSEVI, ZEPATIER

PA Indication Indicator

All Medically-accepted Indications

Off-label Uses

**Exclusion Criteria** 

HEPATITIS C TREATMENT

**Required Medical Information** 

Documentation of chronic hepatitis C infection, HCV RNA level and genotype, Child-

Pugh class

Age Restrictions

**Prescriber Restrictions** 

Infectious disease physician, Gastroenterologist or Hepatologist

**Coverage Duration** 12 to 24 weeks based on drug and indication

Other Criteria

Criteria will be applied consistent with current AASLD/IDSA guidance

Prior Authorization Group HEREDITARY ANGIOEDEMA

**Drug Names** CINRYZE, ORLADEYO, RUCONEST

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -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 C1g levels.

Age RestrictionsCinryze-6 years and older, Ruconest-13 years and older, Orladeyo-12 years and olderPrescriber RestrictionsAllergist, immunologist or hematologistCoverage Duration6 months initial, extension 12 months

Other Criteria Ruconest will only be approved for the treatment of acute attacks. Extensions of

therapy must identify disease state improvement. For Cinryze or Orladeyo, extensions of therapy must identify disease state improvement (such as a decrease in the number,

severity, and/or duration of acute hereditary angioedema attacks)

Prior Authorization GroupHETLIOZDrug NamesHETLIOZ

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Diagnosis of non-24-hour sleep-wake disorder, or for the treatment of nighttime sleep

disturbances in patients with Smith-Magenis syndrome. Sleep disturbance cannot be explained by other current sleep disorder, medical or neurological disorder, mental

disorder, medication use of substance use disorder.

Age 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 Drug Names

PA Indication Indicator
Off-label Uses
Exclusion Criteria
Required Medical Information

**HUMIRA** 

HUMIRA, HUMIRA PEDIATRIC CROHNS D, HUMIRA PEN, HUMIRA PEN-CD/UC/HS START, HUMIRA PEN-PEDIATRIC UC S, HUMIRA PEN-PS/UV STARTER All Medically-accepted Indications

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A. For Rheumatoid Arthritis: documentation of moderately to severely active rheumatoid arthritis with an inadequate response or intolerance to methotrexate or one other DMARD if methotrexate is contraindicated. A prior trial with methotrexate is not required if documentation of acute, aggressive, very rapidly progressive inflammatory symmetrical arthritis disease is provided. B. For moderately to severely active polyarticular juvenile idiopathic arthritis: documentation of an inadequate response or intolerance to 1 DMARD. C. For Psoriatic Arthritis: documentation of active psoriatic arthritis with an inadequate response or intolerance to methotrexate or other diseasemodifying antirheumatic drugs (DMARDs), and 1 NSAID trial. D. For Plague psoriasis: documentation of 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 Ankylosing Spondylitis: documentation of active ankylosing spondylitis or axial spondylarthritis. with an inadequate response or intolerance to 1 NSAID trial, and failure of a 12 week trial of sulfasalazine at maximum tolerated doses in patients with persistent peripheral arthritis. No trial of DMARDS is required for pure axial manifestations. F. For Chrohn's disease or Ulcerative Colitis: documentation of moderate to severely active disease. Patient must be intolerant to 2 different drug classes (examples such as, but not limited to, corticosteroids and immunomodulators such as azathioprine or mercaptopurine). G. For Hidradenitis Suppurativa (HS): documentation of moderate to severe hidradenitis suppurativa. H. For Uveitis: documentation of non-infectious uveitis (including intermediate, posterior, and panuveitis)

Age Restrictions
Prescriber Restrictions

Coverage Duration
Other Criteria

-

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

A frequency/dose greater than 40mg every other week is not covered for Crohn's Disease, Ulcerative colitis, Plaque Psoriasis and Uveitis, except for the initial induction period. Continuation of therapy for all indications will require documentation of improvement of clinical signs and symptoms. Concomitant therapy with other biologic or targeted therapies will not be covered.

**Prior Authorization Group** ICATIBANT

**Drug Names** ICATIBANT ACETATE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Documentation of the following must be provided: 1. Laboratory data confirming

diagnosis of hereditary angioedema (HAE) with one 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 icatibant 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 Allergist, immunologist, or hematologist

Coverage Duration 3 month intervals

Other Criteria Not to be used in combination with Kalbitor or Berinert.

Prior Authorization Group Drug Names

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

PA Indication Indicator
Off-label Uses
Exclusion Criteria
Required Medical Information

All Medically-accepted Indications

Myasthenia gravis w/ acute severe decompensation when 2 standard treatments 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. 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 treatment. 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 treatments 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 treatment 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. Guillain-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

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.

corticosteroids. Humoral or vascular allograft rejection: can be used first line.

**Prior Authorization Group INREBIC INREBIC Drug Names** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses **Exclusion Criteria** 

**Required Medical Information** Clinical documentation indicating that the patient has intermediate-2, or high-risk

primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis, with a baseline platelet count of 50 X 109 cells/L or greater. A baseline Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF) total symptom score is recommended for monitoring symptoms during treatment. Symptoms may include fatigue, night sweats, itching, bone pain, fever, weight loss, For Polycythemia Vera, the patient must also have an inadequate response or intolerance to therapy with

hydroxyurea.

Age Restrictions

**Prescriber Restrictions** Oncologist or Hematologist **Coverage Duration** 12 months

Other Criteria More than 120 capsules per 30 days are not covered. For continued therapy, the

> patient must demonstrate a decrease in symptoms evidenced by clinical chart note documentation, or a decrease in the MPN-SAF total symptom score from baseline.

**Prior Authorization Group ITRACONAZOLE Drug Names ITRACONAZOLE** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses

**Exclusion Criteria** Congestive heart failure

**Required Medical Information** For onychomycosis: Positive KOH test from a nail scraping or a positive pathogenic

fungal culture documenting the presence of hyphae consistent with susceptible dermatophytes (tinea unguium). Member is non-immunocompromised (e.g. negative HIV status, not undergoing chemotherapy, not a transplant recipient). Identify location of onychomycosis (e.g. fingernails and/or toenails). For lung fungal infections, start date of itraconazole and: Fungal cultures identifying one of the following1. Blastomycosis. 2.

Histoplasmosis. 3. Aspergillosis.

**Age Restrictions Prescriber Restrictions Coverage Duration** 

Other 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 one formulary topical antifungal product such as topical ketoconazole or topical clotrimazole. Combination therapy with more than one antifungal agent (terbinafine, itraconazole, ciclopirox) will not be covered **Prior Authorization Group Drug Names**JAKAFI
JAKAFI

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

Exclusion Criteria Chronic myelogenous leukemia, myelodysplastic syndrome, or other myeloid

neoplasm.

**Required Medical Information** Clinical documentation indicating that the patient has intermediate or high-risk

myelofibrosis including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. A baseline Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF) total symptom score is recommended for monitoring symptoms during treatment. Symptoms may include fatigue, night sweats, itching, bone pain, fever, weight loss. For Polycythemia Vera, the patient must have an inadequate response or intolerance to therapy with hydroxyurea. For acute graft-versus-host disease (GVHD), the patient must be unresponsive, or refractory to steroid treatment. For continued therapy, the patient must demonstrate a decrease in symptoms evidenced by clinical chart note documentation, or a decrease in the MPN-

SAF total symptom score from baseline.

Age Restrictions

Prescriber Restrictions Oncologist or transplant specialist

Coverage Duration 12 months

Other Criteria -

Prior Authorization Group

Drug Names

JYNARQUE

JYNARQUE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** History, signs or symptoms of significant liver impairment or injury (not including

uncomplicated polycystic liver disease), use in combination with strong CYP3A inhibitors, inability to sense or respond to thirst, uncorrected abnormal blood sodium concentrations, hypovolemia, hypersensitivity to tolvaptan, urinary outflow obstruction,

anuria, patients who have progressed to end-stage renal disease.

**Required Medical Information** Diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by

ultrasound. Total kidney volume (TKV) classification of 1C or higher. Chart notes identifying symptoms of ADPKD such as hypertension and flank pain. Blood sodium

concentrations, ALT, AST, and bilirubin levels prior to starting therapy.

Age Restrictions 18 years and older

Prescriber Restrictions Ordered by or Consult with nephrologist

**Coverage Duration** 3 months. Extended authorizations limited to 6 months

Other Criteria For continuation of therapy, documentation must be provided of continued monitoring

of AST, ALT, and bilirubin monthly for 18 months and every 3 months thereafter.

Prescribers must enroll in the REMS Access program.

Prior Authorization Group KALYDECO Drug Names KALYDECO

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -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 ivacaftor based on clinical and or vitro

assay data. For continuation of therapy, documentation provided must identify

continued benefit supported by one of the following: Improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1. decrease in pulmonary exacerbations or improvement in CF symptoms including

cough, sputum production, and difficulty breathing.

Age Restrictions -

Prescriber RestrictionsPulmonologistCoverage Duration6 months

Other Criteria More than 60 tablets per 30 days are not covered.

Prior Authorization Group Drug Names

KINASE INHIBITORS

AFINITOR DISPERZ, ALECENSA, ALUNBRIG, AYVAKIT, BALVERSA, BOSULIF, BRAFTOVI, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPIKTRA, COTELLIC, EVEROLIMUS, EXKIVITY, FOTIVDA, GAVRETO, ICLUSIG, IMATINIB MESYLATE, IMBRUVICA, INLYTA, IRESSA, KOSELUGO, LENVIMA 10 MG

DAILY DOSE, LENVIMA 12MG DAILY DOSE, LENVIMA 14 MG DAILY DOSE, LENVIMA 18 MG DAILY DOSE, LENVIMA 20 MG DAILY DOSE, LENVIMA 24 MG DAILY DOSE, LENVIMA 4 MG DAILY DOSE, LENVIMA 8 MG DAILY DOSE, LENVI

LORBRENA, LUMAKRAS, MEKINIST, MEKTOVI, NERLYNX, NEXAVAR, PEMAZYRE, PIQRAY 200MG DAILY DOSE, PIQRAY 250MG DAILY DOSE, PIQRAY

300MG DAILY DOSE, QINLOCK, RETEVMO, REZUROCK, ROZLYTREK, RYDAPT, SCEMBLIX, SORAFENIB TOSYLATE, SPRYCEL, STIVARGA, SUNITINIB MALATE, TABRECTA, TAGRISSO, TAZVERIK, TEPMETKO, TRUSELTIQ, TUKYSA, TURALIO,

UKONIQ, VIJOICE, VITRAKVI, VIZIMPRO, XALKORI, XOSPATA, ZELBORAF,

ZYKADIA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Diagnosis for the requested drug, with current clinical documentation of any previous

therapies tried.

Age Restrictions -

**Prescriber Restrictions**Oncologist, transplant specialist, neurologist, or hematologist. For Ayvakit: Allergist,

Immunologist.

Coverage Duration 12 months

Other Criteria -

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**Prior Authorization Group** KINERET **Drug Names** KINERET

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Dosing that exceeds FDA-approved labeling for the indication will not be a covered

benefit.

**Required Medical Information** For Rheumatoid Arthritis: documentation of moderately to severely active rheumatoid

arthritis with an inadequate response or intolerance to Enbrel and Humira. For the treatment of cryopyrin-associated periodic syndromes (CAPS), specifically Neonatal-Onset Multisystem Inflammatory Disease (NOMID): documentation of the specified

disease state, including any supportive laboratory results if available.

Age Restrictions -

Prescriber RestrictionsPrescribed by, or in consultation with, a rheumatologist, immunologistCoverage Duration12 months

Other Criteria For continued therapy: Documentation must be provided with each extension request

indicating improvement, or stability, in the clinical signs and symptoms of the disease

while on treatment.

Prior Authorization Group KORLYM Drug Names KORLYM

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -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** LIDOCAINE PATCH

**Drug Names** LIDOCAINE

**PA Indication Indicator** All FDA-approved Indications, Some Medically-accepted Indications

Off-label Uses Diabetic neuropathy

**Exclusion Criteria** Hypersensitivity to local anesthetics of the amide type (like prilocaine or bupivacaine).

**Required Medical Information** Documentation of diagnosis of post-herpetic neuralgia or diabetic neuropathy.

Age Restrictions 18 years old and older

Prescriber Restrictions -

Coverage Duration 12 months

Other Criteria Documentation must identify diagnosis of the post-herpetic neuralgia or diabetic

neuropathy. Continuation of therapy will require documentation of improvement in the

clinical signs and symptoms described.

Prior Authorization Group LIDOCAINE TOPICAL

Drug NamesLIDOCAINE, LIDOCAINE HCLPA Indication IndicatorAll Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation of diagnosis for use

Age Restrictions --

Coverage Duration 12 months

Other Criteria -

Prior Authorization Group LUPKYNIS
Drug Names LUPKYNIS

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** The safety and efficacy of Lupkynis has not been established in combination with

cyclophosphamide and is not recommended.

**Required Medical Information** Patient has active lupus nephritis, and Lupkynis will be used in combination with

mycophenolate mofetil and corticosteroids, unless there is a significant intolerance, or

contraindication to these medications.

Age Restrictions -

Prescriber Restrictions -

Coverage Duration 12 months

Other Criteria The safety and efficacy of Lupkynis has not been established beyond 12 months of

therapy and will not be covered.

**Prior Authorization Group** MEGESTROL

**Drug Names** MEGESTROL ACETATE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Current clinical documentation indicating the use for megestrol

Age Restrictions 18 years old and older

Prescriber Restrictions -

Coverage Duration 12 months

Other Criteria Non-FDA approved diagnosis will be evaluated according to the CMS medically

accepted indications requirements in Chapter 6 of the Medicare Prescription Drug

**Benefit Manual** 

**Prior Authorization Group** MODAFINIL

Drug NamesARMODAFINIL, MODAFINILPA Indication IndicatorAll Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Condition modafinil or armodafinil is being used to treat. Narcolepsy with Excessive

Daytime Sleepiness indication the following is required: Sleep Latency Test results. Obstructive Sleep Apnea indication the following are required: Polysomnography

results

Age Restrictions 17 years old and older

Prescriber Restrictions -

Coverage Duration 12 months

Other Criteria Narcolepsy with Excessive Daytime Sleepiness-patients must have had a positive

Multiple Sleep Latency Test (MSLT). Obstructive Sleep Apnea-patients must have had a positive Polysomnography. For Shift Work Sleep Disorder the patient's symptoms should not be attributable to any co-morbid medical or mental condition. Continuation of therapy will require documentation of improvement in alertness or relevant clinical sign/symptom. Non-FDA approved diagnosis will be evaluated according to the CMS medically accepted indications requirements in Chapter 6 of the Medicare Prescription

Drug Benefit Manual

Prior Authorization GroupMOVEMENT DISORDERSDrug NamesAUSTEDO, INGREZZA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation indicating the patient has tardive dyskinesia. Clinical signs and

symptoms can include, but are not limited to, loss of muscle control, especially of the

face, arms, and legs, resulting in repetitive involuntary movements.

Age Restrictions -

**Prescriber Restrictions** Restricted to neurologists or psychiatrists

Coverage Duration 12 months

Other Criteria For continued therapy: Documentation of response must be provided with each request

for extension of therapy that identifies improvement in the clinical signs and symptoms.

Prior Authorization GroupMULPLETADrug NamesMULPLETA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation that the patient has chronic hepatic disease, date of upcoming

procedure, platelet count prior to the procedure

Age Restrictions -

Prescriber Restrictions Ordered by or Consult with a Gastroenterologist, Hepatologist, Hematologist, or

Surgeon.

Coverage Duration 4 weeks

Other Criteria -

Prior Authorization GroupMYALEPTDrug NamesMYALEPT

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**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 lipodystrophy, Nonalcoholic Steatohepatitis (NASH), History of positive anti-metreleptin antibodies, General obesity in absence of generalized lipodystrophy, Diabetes Mellitus in absence of generalized lipodystrophy, Or hypertriglyceridemia in absence of generalized lipodystrophy. AND to be eligible for approval of Myalept therapy the patient MUST have all of the following: Clinical

lipodystrophy (i.e. loss/absence of subcutaneous fat, insulin resistance,

hypertriglyceridemia), Pharmacologic treatment of hypertriglyceridemia has been maximized or cannot be tolerated, Insulin therapy for the treatment of hyperglycemia has been maximized. For continued therapy: Documentation of response to Myalept

must be provided with each request for extension of therapy that identifies improvement in the HbA1c, triglycerides and fasting glucose from baseline.

Prior Authorization Group NATPARA
Drug Names NATPARA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Diagnosis of hypoparathyroidism. Documentation of sufficient 25-hydroxyvitamin D

stores and a corrected serum calcium above 7.5mg/dL before initiated therapy. Serum

calcium and 25-hydroxyvitamin D levels with each extension request.

Age Restrictions 18 years old and older

Prescriber Restrictions Endocrinologist

Coverage Duration 3 months initial, extension 12 months

Other Criteria For extensions of therapy must maintain a corrected serum calcium concentration

between 7.5 and 10.6 mg/dL

Prior Authorization Group NUEDEXTA

Drug Names NUEDEXTA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**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

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -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 GroupODACTRADrug NamesODACTRA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Severe, unstable or uncontrolled asthma. History of eosinophilic esophagitis. History of

any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy. Will not be covered if receiving subcutaneous allergen immunotherapy

**Required Medical Information** Patient has documented allergic rhinitis with or without conjunctivitis induced by house

dust mite (HDM) allergen. Hypersensitivity to house dust mite (HDM) allergen should be confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts prior to use. Documentation must identify failure of at least TWO of the following treatments: an intranasal corticosteroid, oral antihistamine, or an

oral leukotriene receptor antagonist.

Age Restrictions Adults 18 through 65 years of age

Prescriber Restrictions -

Coverage Duration 12 months

Other Criteria For continuation of treatment, the benefits of treatment (decrease of symptoms,

increase tolerance to HDM allergen) must be documented.

Prior Authorization GroupODOMZODrug NamesODOMZO

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - 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

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Documented diagnosis of idiopathic pulmonary fibrosis (IPF), scleroderma (systemic

sclerosis)-associated interstitial lung disease (SSc-ILD), or chronic fibrosing interstitial

lung disease (ILD) with a progressive phenotype. High resolution computed tomography (HRCT) results, PE findings and liver function tests if available.

Age Restrictions -

Prescriber Restrictions Ordered by, or by consult with, a pulmonologist.

Coverage Duration 6 months

Other Criteria For continuation of therapy, the documentation must identify an improvement or

maintenance of disease.

**Prior Authorization Group** OPSUMIT - PENDING CMS REVIEW

**Drug Names** OPSUMIT

PA Indication Indicator

Off-label Uses

Exclusion Criteria

Required Medical Information

Age Restrictions

Prescriber Restrictions Coverage Duration Other Criteria -

Prior Authorization Group ORKAMBI
Drug Names ORKAMBI

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

Required Medical Information Chart notes identifying diagnosis of cystic fibrosis and test results identifying a

homozygous F508del mutation in the CFTR gene. Baseline ppFEV1 results, BMI and

number of pulmonary exacerbations in the past 6 months.

**Age Restrictions** 2 years old and older

Prescriber RestrictionsPulmonologistCoverage Duration6 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 OTEZLA OTEZLA Drug Names** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses **Exclusion Criteria** 

For Psoriatic Arthritis: documentation of active psoriatic arthritis with an inadequate **Required Medical Information** 

response or intolerance to methotrexate or other disease-modifying antirheumatic

drugs (DMARDs), and 1 NSAID trial.

Age Restrictions **Prescriber Restrictions Coverage Duration** Other Criteria

Prescribed by, or in consultation with, a dermatologist, rheumatologist, immunologist

12 months

For continued therapy: Documentation of response to Otezla must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms. Concomitant treatment with other biologic therapies will not be covered.

**Prior Authorization Group** 

**POSACONAZOLE Drug Names** NOXAFIL, POSACONAZOLE DR **PA Indication Indicator** All Medically-accepted Indications

Off-label Uses **Exclusion Criteria** 

**Required Medical Information** 

Documentation indicates the patient requires posaconazole for one of the following: 1) For the prophylaxis of invasive Aspergillus infections in severely immunocompromised patients who are at high risk of infection. 2) For the prophylaxis of invasive Candida infections in severely immunocompromised patients who are at high risk of infection. 3) For the treatment of oropharyngeal candidiasis, refractory to itraconazole and/or fluconazole. 4) For the treatment of invasive aspergillosis

Age Restrictions **Prescriber Restrictions Coverage Duration** Other Criteria

3 months for treatment, 12 months for prophylaxis

Additional indications for posaconazole (i.e., salvage therapy) will be reviewed based on current references in Medicare approved compendia. Requests for extension will require current clinical chart notes for the documentation of continued medical necessity.

Prior Authorization GroupPRALUENTDrug NamesPRALUENT

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Request is for an FDA approved indication

Age Restrictions - Prescriber Restrictions -

Coverage Duration 12 months

Other Criteria Patient must have a previous trial, intolerance, or contraindication to a high intensity

statin such as atorvastatin 40mg or rosuvastatin 20mg, OR the patient is already

established on Praluent therapy.

Prior Authorization Group
Drug Names
PA Indication Indicator

Off-label Uses
Exclusion Criteria

PROMACTA

**PROMACTA** 

All Medically-accepted Indications

-

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

Gastroenterologist, Hematologist, Infectious Disease Specialist Initial approval will be for 3 months. Extensions of therapy - 12 months For the diagnosis of chronic immune idiopathic thrombocytopenia purpura: Degree of thrombocytopenia and clinical condition puts member at an increased risk of bleeding, AND failure or contraindication to the following: 1. IVIG, 2. corticosteroids. For continuation of therapy: a) current platelet count is less than or equal to 200,000/mcL OR b) current platelet count is greater than 200.000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding. For the diagnosis of thrombocytopenia in patients with chronic hepatitis C: degree of thrombocytopenia does not allow member to start interferon-based therapy. For continuation of therapy: patient is receiving interferon-based therapy. For severe aplastic anemia: may be used in combination with standard immunosuppressive therapy for first-line treatment, or for patients who have had an inadequate response to immunosuppressive therapy. For continuation: a) current platelet count is less than or equal to 200,000/mcL OR b) current platelet count is greater than 200,000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding. For all indications, the platelet count must not exceed 400x 10 to the 9th/L after 2 weeks of therapy at lowest FDA approved dose.

Prior Authorization GroupPYRIMETHAMINEDrug NamesPYRIMETHAMINE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Megaloblastic anemia due to folate deficiency

**Required Medical Information** Chart notes identifying pyrimethamine 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 - 12 months

Other Criteria For the prophylaxis of Toxoplasmosis, and prophylaxis or treatment of PCP -must have

contraindication to the use of trimethoprim-sulfamethoxazole. For the prophylaxis or treatment of malaria must have failed therapy with, or have a contraindication to the

use of atovaquone-proguanil and mefloquine

Prior Authorization Group RIBAVIRIN Drug Names RIBAVIRIN

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

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

hemoglobinopathies.

**Required Medical Information** HCV RNA level and genotype

Age Restrictions -

Prescriber Restrictions -

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

Other Criteria 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 RINVOQ RINVOQ Drug Names** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses **Exclusion Criteria** 

**Required Medical Information** 

For Rheumatoid Arthritis: documentation of moderately to severely active rheumatoid arthritis with an inadequate response or intolerance to methotrexate or one other DMARD if methotrexate is contraindicated. A prior trial with methotrexate is not required if documentation of acute, aggressive, very rapidly progressive inflammatory symmetrical arthritis disease is provided. For Psoriatic Arthritis: documentation of active psoriatic arthritis with an inadequate response or intolerance to Enbrel or Humira. For Atopic Dermatitis: documentation of refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when the use of those therapies are inadvisable. For Ulcerative Colitis: documentation of moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to Humira. For Ankylosing Spondylitis: documentation of active ankylosing spondylitis with an inadequate response or intolerance to Enbrel or Humira

Age Restrictions **Prescriber Restrictions Coverage Duration** Other Criteria

Restricted to rheumatologists, immunologists, dermatologists or gastroenterologists. 12 months

Continuation of therapy will require documentation of improvement in the clinical signs and symptoms of the disease. Concomitant therapy with other biologic or targeted therapies will not be covered.

**Prior Authorization Group** SAPROPTERIN

Drug NamesSAPROPTERIN DIHYDROCHLORIPA Indication IndicatorAll Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria**The use of sapropterin 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 sapropterin treatment after one month of treatment at the maximum dose). Not

maintaining Phe levels below baseline. Previous failure of sapropterin.

**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-

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 sapropterin 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 RestrictionsSpecialist or prescriber with experience in PKUCoverage Duration2 months initial approval, extension 6 months

Other Criteria -

**Prior Authorization Group** SHORT BOWEL SYNDROME

**Drug Names** GATTEX, ZORBTIVE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** For Zorbtive- patients with active neoplasia

**Required Medical Information** Documentation indicates the patient is dependent on parenteral nutritional support.

Age Restrictions

**Prescriber Restrictions** Gastroenterologist

**Coverage Duration** Zorbtive- 4 weeks. Gattex- Initial approval-3 months, extensions, 6 months.

Other Criteria For continuation: Requirement for parenteral support has decreased from baseline

while on therapy.

**Prior Authorization Group** SILDENAFIL

**Drug Names** SILDENAFIL CITRATE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Coverage will not be provided for the treatment of digital ulcer or erectile dysfunction.

Combination therapy will not be covered for initial therapy.

**Required Medical Information** Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial

(FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying: resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients.(Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of

therapy is dependent upon documentation of clinical response

**Age Restrictions** 18 years old and older

Prescriber Restrictions Ordered by or Consult with pulmonologist or cardiologist

Coverage Duration Initial approval 4 months, extensions 12 months

Other Criteria -

**Prior Authorization Group** SKYRIZI

**Drug Names** SKYRIZI, SKYRIZI PEN

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** For Plague psoriasis: documentation of moderate to severe chronic plague psoriasis

OR involvement of the palms, soles of feet and scalp. An appropriate trial was not effective or contraindicated with one of the following: methotrexate, oral retinoids,

cyclosporine.

Age Restrictions

Prescriber Restrictions
Coverage Duration

Other Criteria

Restricted to immunologists, dermatologists, gastroenterologists, and rheumatologists.

12 months

Continuation of therapy will require documentation of improvement in the clinical signs

and symptoms of the disease. Concomitant therapy with other biologic or targeted

therapies will not be covered.

Prior Authorization GroupSTELARADrug NamesSTELARA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** For Plaque Psoriasis: documentation of moderate to severe chronic plaque psoriasis

OR involvement of the palms, soles of feet and scalp, with an inadequate response, intolerance, or contraindication with TWO of the following therapies: Enbrel, Humira,

Otezla, Skyrizi.

For Psoriatic Arthritis: documentation of active psoriatic arthritis with an inadequate response or intolerance to TWO of the following therapies: Enbrel, Humira, Otezla, Xeljanz/XR. For Crohn's disease: documentation of moderate to severely active disease, with a previous trial, intolerance, or contraindication to Humira. For Ulcerative Colitis: documentation of moderately to severely active ulcerative colitis, with an inadequate response, intolerance, or contraindication to Humira and Xeljanz/XR.

Age Restrictions -

**Prescriber Restrictions** Prescribed by, or in consultation with, a dermatologist, rheumatologist, or

gastroenterologist

Coverage Duration 12 months

Other Criteria For continued therapy: Documentation of response to Stelara must be provided with

each request for extension of therapy that identifies improvement or stability in the

clinical signs and symptoms.

Prior Authorization Group SYMDEKO
Drug Names SYMDEKO

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation indicates the patient has a diagnosis of cystic fibrosis (CF) that is

homozygous for the F508del mutation OR has at least 1 mutation in the CFTR gene that is responsive to tezacaftor, ivacaftor. If the patient's genotype is unknown, an FDA-cleared CF mutation test is recommended. A baseline percent predictive pre-dose

FEV1 should be obtained prior to therapy.

Age Restrictions

Prescriber RestrictionsPulmonologistCoverage Duration6 monthsOther CriteriaMore than 60 to

More than 60 tablets per 30 days are not covered.

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 the percent predicted pre-dose FEV1, decrease in pulmonary exacerbations or improvement in CF symptoms including

cough, sputum production, and difficulty breathing.

**Prior Authorization Group** TADALAFIL FOR BPH

**Drug Names** TADALAFIL

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Concomitant use of nitrate-based drugs (nitroglycerin) for heart conditions,

Hypersensitivity reaction to tadalafil

**Required Medical Information** Tadalafil 2.5mg or 5mg may be considered medically necessary when the following

criteria are met: Clinical documentation indicates the patient has symptomatic BPH, with failure, or intolerance to a trial of: an alpha-blocker, a 5-alpha-reductase inhibitor, OR the patient has a contraindication to both of these therapies. For continued therapy:

clinical documentation indicates a reduction in symptoms.

Age Restrictions 18 years old and older

Prescriber Restrictions Restricted to urologists (or urology consult identified)

**Coverage Duration** Remainder of the contract year.

Other Criteria Will not be covered solely for: erectile dysfunction (ED) for standard plans, status post

radical prostatectomy, in combination with other PDE 5 inhibitors or solely to reduce PSA level. The use of tadalafil 2.5mg tablets will be approved for members with a creatinine clearance of 30 to 50mL/min or in patients that are unable to tolerate the

5mg dose

**Prior Authorization Group** TADALAFIL FOR PAH

**Drug Names** ALYQ, TADALAFIL

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

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.

**Required Medical Information** Verification of WHO Group I pulmonary hypertension due to idiopathic (IPAH), familial

(FPAH), drugs or toxins, connective tissue diseases, HIV infection, congenital heart disease, schistosomiasis, sickle cell disease, or a condition that affects the veins and small blood vessels of the lungs. Right sided catheterization identifying: resting mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg, and pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Vasoreactive testing is recommended for all PAH patients.(Documentation with rationale must be provided for patients that have not been tested). Previous and current therapies. Extension of therapy is dependent upon documentation of clinical response and lack of deterioration

Age Restrictions 18 years and older

**Prescriber Restrictions**Ordered by or consult with pulmonologist or cardiologist

Coverage Duration Initial 4 months with 12 month extensions

Other Criteria -

Prior Authorization GroupTAKHZYRODrug NamesTAKHZYRO

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation of the following must be provided: 1. Laboratory data confirming

diagnosis of hereditary angioedema (HAE) with on of the following: a.C1-INH and serum complement factor 4 level below the reference range along with a serum C1q level within normal reference range, OR b. C1-INH level that is normal or elevated but dysfunctional, low C4 level and normal C1q level, OR c. Normal C1-INH with normal functional assay and normal C4 and C1q levels AND Family history of HAE, if any. 2. Medications that may trigger or worsen angioedema have been evaluated and discontinued if appropriate. (Examples of these are estrogen contraceptives, hormone replacement therapy, and ACE-Inhibitors.) 3. Member is not currently receiving medications that may trigger or worsen angioedema. 4. Member has a history of at 1 acute HAE attack per month. For continued use, the following documentation must be identified following Takhzyro use: diminished symptoms, decreased severity of attacks, reduced duration of attacks, and decreased hospitalizations when compared to previous therapies. Please provide date of last attack.

Age Restrictions 12 years and older

Prescriber Restrictions Allergist, immunologist, or hematologist

Coverage Duration3 months. Extended authorizations limited to 6 monthsOther CriteriaNot to be used in combination with Cinryze, or Haegarda.

Prior Authorization Group TALTZ
Drug Names TALTZ

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** For Ankylosing Spondylitis: documentation of active ankylosing spondylitis, or active,

non-radiographic axial spondyloarthritis with objective signs of inflammation, with an inadequate response, intolerance, or contraindication to ONE the following therapies:

Enbrel or Humira.

For Psoriatic Arthritis: documentation of active psoriatic arthritis with an inadequate response, intolerance, or contraindication to ONE of the following therapies: Enbrel.

Humira, Otezla, Xeljanz/XR.

For Plaque Psoriasis: documentation of moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp, with an inadequate response, intolerance, or contraindication to ONE the following therapies: Enbrel, Humira, Otezla,

Skyrizi.

Age Restrictions

Prescriber Restrictions
Coverage Duration
Other Criteria

Prescribed by, or in consultation with, a dermatologist or rheumatologist

12 months

For continued therapy: Documentation of response to Taltz must be provided with each request for extension of therapy that identifies improvement in the clinical signs and

symptoms.

**Prior Authorization Group** TARGRETIN

Drug Names

BEXAROTENE, TARGRETIN

PA Indication Indicator

All Medically-accepted Indications

Off-label Uses
Exclusion Criteria

**Required Medical Information** Clinical chart notes that indicate the patient requires Targretin gel for the treatment of

cutaneous lesions of stage IA or IB cutaneous T-cell lymphoma, that have refractory or persistent disease after other therapies, or have not tolerated other therapies. Non-FDA

approved diagnoses will be evaluated according to the CMS medically accepted indications requirements in Chapter 6 of the Medicare Prescription Drug Benefit

Manual.

Age Restrictions -

Prescriber Restrictions -

Coverage Duration
Other Criteria

Remainder of the contract year

For continued therapy: Documentation of response must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms.

**Prior Authorization Group TEGSEDI TEGSEDI Drug Names** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses **Exclusion Criteria** 

**Required Medical Information** Documentation of the following must be provided: 1. Patient has documented

transthyretin (TTR) mutation as confirmed through genetic testing AND Presence of

polyneuropathy characterized by ONE of the following:

i. Baseline polyneuropathy disability (PND) score less than IIIb ii. Baseline FAP (familial amyloid polyneuropathy) Stage 1 or 2.

2. Patient has a platelet count greater than 100 x 109/L

Age Restrictions 18 years and older

**Prescriber Restrictions Coverage Duration** Other Criteria

Neurologist, immunologist, or physician who specializes in the treatment of amyloidosis

3 months. Extended authorizations limited to 6 months

For continuation of therapy, clinical documentation showing the patient has experienced a positive clinical response to Tegsedi (ie, improved neurologic impairment, motor function, cardiac function, quality of life assessment) must be

identified

**TETRABENAZINE Prior Authorization Group TETRABENAZINE Drug Names** 

PA Indication Indicator All Medically-accepted Indications

Off-label Uses

Concomitant use with reserpine or use of reserpine within the past 20 days. Members **Exclusion Criteria** 

with liver disease. Uncontrolled or untreated depression.

Chart notes including: baseline and any subsequent total Chorea Score or the Unified **Required Medical Information** 

> 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 continued therapy: Documentation of

response must be provided with each request.

Age Restrictions 18 years old and older **Prescriber Restrictions** Restricted to neurologists

**Coverage Duration** 

Initial approval for 3 months. Continuation of therapy six months. Other Criteria

For doses above 50mg per day testing must be provided identifying patient is an

extensive or intermediate metabolizer of CYP2D6.

Prior Authorization GroupTOBI PODHALERDrug NamesTOBI PODHALER

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**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 TOLVAPTAN
Drug Names TOLVAPTAN

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**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 that the patient has clinically significant hypervolemic and euvolemic

hyponatremia (serum sodium less than 125 mEq/L or hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH). Tolvaptan must be

initiated in a hospital setting.

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

tolvaptan. Tolvaptan should not be used longer than 30 days.

Prior Authorization Group TRETINOINS
Drug Names TRETINOIN

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

**Exclusion Criteria** Cosmetic use including wrinkles.

**Required Medical Information** The use of topical tretinoins will be considered medically necessary if all of the

following criteria are met: Diagnosis of acne vulgaris. Subsequent requests will be

considered if there is documentation of: Improvement in acne lesions.

Age Restrictions 10 years old and older

Prescriber Restrictions -

Coverage Duration Remainder of contract year

Other Criteria Failure of a one month trial of each of the following: combination formulary agent

containing topical erythromycin and benzoyl peroxide. Combination formulary agent

containing topical clindamycin and benzoyl peroxide.

**Prior Authorization Group** TRIENTINE

Drug NamesTRIENTINE HYDROCHLORIDEPA Indication IndicatorAll Medically-accepted Indications

Off-label Uses - 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** TRIKAFTA **Drug Names** TRIKAFTA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation indicates the patient has a diagnosis of cystic fibrosis (CF) with at least

one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. If the patient's genotype is unknown, an FDA- cleared CF mutation test is recommended. A baseline percent predictive pre-dose FEV1 should be obtained prior

to therapy.

Age Restrictions -

Prescriber RestrictionsPulmonologistCoverage Duration6 monthsOther CriteriaMore than 84 trees

More than 84 tablets per 28 days are not covered.

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 the percent predicted pre-dose FEV1, decrease in pulmonary exacerbations or improvement in CF symptoms including

cough, sputum production, and difficulty breathing.

Prior Authorization Group UPTRAVI
Drug Names UPTRAVI

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - 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 GroupVALCHLORDrug NamesVALCHLOR

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - 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

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - 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 VONJO Drug Names VONJO

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Clinical documentation indicating that the patient has intermediate or high-risk primary

or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis

(MF), with a platelet count below 50 X 109 cells/L. A baseline Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF) total symptom score is

recommended for monitoring symptoms during treatment. Symptoms may include

fatigue, night sweats, itching, bone pain, fever, weight loss.

Age Restrictions

Prescriber RestrictionsHematologist or OncologistCoverage Duration12 months

Other Criteria More than 120 capsules per 30 days are not covered. For continued therapy, the

patient must demonstrate an increase in platelet count, or a decrease in symptoms evidenced by clinical chart note documentation or a decrease in the MPN-SAF total

symptom score from baseline.

Prior Authorization GroupVORICONAZOLEDrug NamesVORICONAZOLE

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Request is for an FDA approved indication, or an indication supported in the CMS

recognized compendia

Age Restrictions - Prescriber Restrictions -

Coverage Duration 6 months

Other Criteria -

**Prior Authorization Group** VYNDAQEL

**Drug Names** VYNDAMAX, VYNDAQEL

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** Documentation indicating the patient has wild type or hereditary transthyretin amyloid

cardiomyopathy

**Age Restrictions** 18 years of age and older

**Prescriber Restrictions**Neurologist, cardiologist, or physician who specializes in the treatment of amyloidosis **Coverage Duration**Neurologist, cardiologist, or physician who specializes in the treatment of amyloidosis

3 months. Extended authorizations limited to 6 months

5 months. Extended authorizations inflited to 6 months

**Other Criteria**For continued therapy: Documentation of response must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms.

Prior Authorization Group WAKIX
Drug Names WAKIX

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation indicates the patient has narcolepsy with Excessive Daytime

Sleepiness (EDS) or cataplexy. For excessive daytime sleepiness, the patient must have an intolerance, contraindication, or failure to a one-month trial of the following at

the maximum tolerated dose: modafinil OR armodafinil AND a formulary

methylphenidate product.

Age Restrictions -Prescriber Restrictions --

Coverage Duration Initial approval: 3 months. Continued therapy: 12 months

Other Criteria For continued therapy: Request for extension indicates an improvement in symptoms.

More than 60 tablets per 30 days are not covered.

**Prior Authorization Group** XELJANZ

**Drug Names** XELJANZ, XELJANZ XR

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** For Rheumatoid Arthritis: documentation of moderately to severely active rheumatoid

arthritis with an inadequate response or intolerance to methotrexate or one other DMARD if methotrexate is contraindicated. For Psoriatic Arthritis: documentation of active psoriatic arthritis with an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs), and 1 NSAID trial. For Ulcerative Colitis: documentation of moderately to severely active ulcerative colitis. Patient must be intolerant to 2 different drug classes (examples such as, but not limited to, corticosteroids and immunomodulators such as azathioprine or mercaptopurine).

Age Restrictions -

**Prescriber Restrictions** Prescribed by, or in consultation with, a rheumatologist, immunologist, or

gastroenterologist

Coverage Duration 12 months

Other Criteria The use of Xeljanz or Xeljanz XR in combination with biologic DMARDs or potent

immunosuppressants such as azathioprine and cyclosporine is not recommended. For continued therapy: Documentation of response to Xeljanz must be provided with each request for extension of therapy that identifies improvement in the clinical signs and

symptoms.

Prior Authorization Group XERMELO Drug Names XERMELO

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** For the treatment of carcinoid syndrome diarrhea in combination with somatostatin

analog (SSA) therapy in patients inadequately controlled by SSA therapy

Age Restrictions -

Prescriber RestrictionsPrescribed by, or in consultation with, an oncologist or gastroenterologistCoverage Duration12 monthsOther CriteriaFor continued therapy; documentation of response must be provided with

For continued therapy: documentation of response must be provided with each request for extension of therapy that identifies improvement or stability in the clinical signs and symptoms. Treatment exceeding 250mg three times daily is not a covered benefit.

**Prior Authorization Group** XGEVA **Drug Names** XGEVA

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** Documentation indicates the patient requires Xgeva (denosumab) for one of the

following indications:1) For the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. 2) For the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, 3) For the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Age Restrictions Prescriber Restrictions Coverage Duration 12 months

Other Criteria For continued therapy: Documentation of response must be provided with each request

for extension of therapy that identifies improvement in the clinical signs and symptoms.

Prior Authorization GroupXIFAXANDrug NamesXIFAXAN

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -

Other Criteria

Exclusion Criteria Will not be covered for prophylactic use or diverticular disease.

**Required Medical Information** For diagnosis of active non-invasive travelers diarrhea (TD): Moderate to severe

distressing symptoms of travelers diarrhea are present and proven or strongly suspected to be caused by Escherichia coli based upon symptoms and travel destination. (When culture and susceptibility information are available, culture must identify E. coli and susceptible to rifaximin). For diagnosis of hepatic encephalopathy (HE) and Irritable Bowel Syndrome with Diarrhea (IBS-D): current and previous

therapies tried.

Age Restrictions 12 years old and older

Prescriber Restrictions 
Coverage Duration TD=3 days. HE=6 month

ration 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 Group XOLAIR
Drug Names XOLAIR

PA Indication Indicator All Medically-accepted Indications

Off-label Uses - Exclusion Criteria -

**Required Medical Information** For asthma: documented evidence of reversible airway disease, IgE level, test results

identifying allergic sensitivity to perennial aeroallergens, previous and current therapy. For Chronic idiopathic urticaria (CIU): Duration of urticaria, previous and current therapy. For add-on maintenance treatment of chronic rhinosinusitis with nasal polyps: documentation indicates the disease is inadequately controlled with nasal steroids.

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 agonist or leukotriene inhibitor or theophylline unless contraindicated, IgE level must be between 30 and 1300 IU/ml. For CIU: Urticaria must be present for at least 6 weeks and other causes such as occupational, food, medication, etc. must have been ruled out, must have failed a minimum of a 2 week trial of the maximally tolerated dose of a potent H1 antihistamine in combination with a H2 antihistamine, a systemic corticosteroid or leukotriene receptor antagonist unless contraindicated For continuation of therapy: clinical documentation showing a positive clinical response must be identified.

Prior Authorization Group XYREM Drug Names XYREM

PA Indication Indicator All Medically-accepted Indications

Off-label Uses -Exclusion Criteria -

**Required Medical Information** The use of Xyrem will be considered medically necessary when the medical information

provided documents the following: Definitive diagnosis of narcolepsy based upon objective sleep studies, AND Quantitatively documented symptoms of excessive daytime sleepiness and/or cataplexy, AND no history of GHB abuse, AND no concomitant use with sedative hypnotics (including anxiolytics) or CNS depressants and daily dose does not exceed 9 grams. Continued therapy will be considered based on demonstrated response of decreasing cataplexy events and improvement in score for appropriate test (e.g. Epworth Sleepiness Scale, Clinical Global Impression of Change, etc.) for EDS.

Age Restrictions
Prescriber Restrictions
Coverage Duration
Other Criteria

Initial approval: 3 months. Continued therapy: 6 months

Documented intolerance, contraindication, or failure of a 1 month trial of the following at the maximum tolerated dose: For excessive daytime sleepiness (EDS), modafinil or

armodafinil, AND a formulary methylphenidate product.