Medicare Part D Prior Authorization Criteria

Prior Authorization Group: ACTHAR

Drug Names: ACTHAR

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

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

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

Age Restrictions -

Prescriber Restrictions -

Coverage Duration: 3 months

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

Prior Authorization Group
ACTIMMUNE
Drug Names
ACTIMMUNE
Covered Uses
All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria
-
Required Medical Information
Supporting documentation including prescription history with intravenous antibiotics, complete blood count (CBC) with differential identifying anemia or thrombocytopenia. Documented diagnosis of Chronic Granulomatous Disease (CGD) and continued frequent serious infectious episodes while receiving prophylactic antibiotics, OR Diagnosis of severe, malignant osteopetrosis supported by radiological reports, documentation of previous therapy with intravenous antibiotics, and other relevant clinical findings that were used to diagnosis osteopetrosis and which will be monitored for outcomes such as: anemia, thrombocytopenia, splenomegaly, optic atrophy, chronic osteomyelitis. Continued therapy will be considered based on demonstrated response identified by reduction in serious infections requiring intravenous antibiotics (CGD), reduction in hospitalizations due to serious infections (CGD), increase in hemoglobin and platelet counts (osteopetrosis), no more than 50dB decrease in hearing and no evidence of progressive optic atrophy (osteopetrosis), no evidence of a serious bacterial infection requiring antibiotics (osteopetrosis).

Age Restrictions
-
Prescriber Restrictions
Coverage Duration
3 months initial approval. Remainder of calendar year for extension of therapy
Other Criteria
Actimmune is not covered for idiopathic pulmonary fibrosis

Prior Authorization Group
ADAGEN
Drug Names
ADAGEN
Covered Uses
All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria
-
Required Medical Information
Baseline plasma enzyme adenosine deaminase (ADA) activity confirming diagnosis of ADA deficiency, AND Baseline level of deoxyadenosine triphosphate (dATP) in erythrocytes confirming diagnosis of ADA deficiency, AND Documentation of severe combined immunodeficiency disease, AND Not a suitable candidate for BMT OR failure of BMT. Extension of therapy will be considered if the plasma ADA activity is maintained between 15-35micromol/hr/mL.

Age Restrictions
-
Prescriber Restrictions
Coverage Duration
12 months
Other Criteria
-
<table>
<thead>
<tr>
<th><strong>Prior Authorization Group</strong></th>
<th>ADCIRCA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Names</strong></td>
<td>ADCIRCA, ALYQ, TADALAFIL</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>Concomitant use of organic nitrates or guanylate cyclase stimulators. Will not be covered for the treatment of digital ulcers, erectile dysfunction, or in combination therapy with other phosphodiesterase 5 inhibitors. Combination therapy with other PAH agents will not be covered for initial therapy</td>
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<tr>
<td><strong>Required Medical Information</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>18 years and older</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Ordered by or consult with pulmonologist or cardiologist</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>Initial 4 months with 12 month extensions</td>
</tr>
<tr>
<td><strong>Other Criteria</strong></td>
<td>-</td>
</tr>
</tbody>
</table>
**Prior Authorization Group**  
ADEMPAS

**Drug Names**  
ADEMPAS

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

**Exclusion Criteria**  
Coverage will not be provided if any of the following are true: Use in pregnancy,  
Co-administration of Adempas with a phosphodiesterase inhibitor, including specific  
PDE-5 inhibitors (i.e. sildenafil, tadalafil, vardenafil), nonspecific PDE inhibitors (i.e.  
theophylline or dipyridamole), nitrates or nitric oxide donors. Presence of pulmonary  
veno-occlusive disease

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

**Age Restrictions**  
18 years old and older

**Prescriber Restrictions**  
Cardiologist or pulmonologist

**Coverage Duration**  
Initial 4 months with 12 month extensions

**Other Criteria**  
For WHO Group 1 (new starts only), documentation is required demonstrating failure or  
inadequate response to a trial of one of the following: Orally administered PDE-5  
inhibitor approved for the treatment of PAH (i.e. tadalafil or sildenafil) or Endothelin  
receptor antagonist-Letairis, Tracleer, or Opsumit. Combination therapy with other PAH  
agents will not be covered for initial therapy. Doses greater than the FDA approved  
maximum dose will not be covered
Prior Authorization Group: ALDURAZYME

Drug Names: ALDURAZYME

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

Exclusion Criteria: -

Required Medical Information:
- Diagnosis of Hurler or Hurler-Scheie forms of MPS 1 OR diagnosis of Scheie form with moderate to severe symptoms. Baseline forced vital capacity (FVC) less than 80% and ongoing FVC showing improvement with treatment. Distance walked in 6 minutes (6 minute walk test, 6MWT) at baseline and showing improvement with treatment.
- Documented deficiency in iduronate-2-sulfatase enzyme activity confirming diagnosis of Mucopolysaccharidosis I. Extension of therapy: documentation supports continued benefit based upon improvement in FVC and 6MWT.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration: 6 months

Other Criteria:
- Dose and frequency outside of the FDA approved limits will not be covered

Prior Authorization Group: ALPHA1-ANTITRYPSIN REPLACEMENT THERAPY

Drug Names: ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

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

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

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

Age Restrictions:

Prescriber Restrictions: Must be ordered or followed by a pulmonologist

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

Other Criteria: -
**Prior Authorization Group**

**AMPYRA**

**Drug Names**

AMPYRA, DALFAMPRIDINE ER

**Covered Uses**

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

**Exclusion Criteria**

Prior history of seizure. Moderate or severe renal impairment defined as a creatinine clearance (CrCl) of less than or equal to 50 mL/min. History of hypersensitivity to Ampyra or 4-aminopyridine. Use with 4-aminopyridine or fampridine

**Required Medical Information**

Neurology chart notes must be provided including all radiologic reports supporting the dx of MS. Prior to dalfampridine treatment timed 25-foot walk (T25FW) result. (Assistive devices must be consistently used across pre-treatment walk tests and identified in the chart notes.) For continuation of therapy for second request: Current T25FW result be provided showing an improvement over the baseline average. Continuation thereafter: T25FW result identifying a continued improvement over the fastest baseline maximum speed. Individuals must maintain initial improvement over baseline in T25FW at each extension.

**Age Restrictions**

18 years old and older

**Prescriber Restrictions**

Restricted to neurologists

**Coverage Duration**

Initial: 3 months. Continuation 12 months

**Other Criteria**

Currently receiving a stable dose of disease-modifying therapy for RRMS (or on a stable dose of disease-modifying therapy for all other forms of MS if appropriate) for at least 60 days (e.g. no changes in therapy for 60 days prior to start of dalfampridine treatment). Continued approval of Ampyra will not be allowed if the T25FW declines from baseline. Will not be covered for the prevention of symptoms

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**Prior Authorization Group**

**ANTIDEPRESSANTS**

**Drug Names**

FETZIMA, FETZIMA TITRATION PACK, TRINTELLIX

**Covered Uses**

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

**Exclusion Criteria**

Use in combination with MAOIs or linezolid.

**Required Medical Information**

Documentation identifying diagnosis of major depressive disorder. Previous therapies tried

**Age Restrictions**

18 years old and older

**Prescriber Restrictions**

- 

**Coverage Duration**

12 months.

**Other Criteria**

Documentation must include failure or inadequate response to a minimum of a 6 week trial of two of the following: Citalopram, Escitalopram, Fluoxetine, Paroxetine, Sertraline, Trazodone, Venlafaxine, Duloxetine
Prior Authorization Group: ANTIMETABOLITES

Drug Names: ALIMTA, LONSURF, VYXEOS, ZALTRAP

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

Exclusion Criteria: -

Required Medical Information: Documentation of diagnosis for use, current chart notes and any previous and concurrent therapies

Age Restrictions: -

Prescriber Restrictions: Oncologist

Coverage Duration: 12 months

Other Criteria: -

Prior Authorization Group: ARCALYST

Drug Names: ARCALYST

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

Exclusion Criteria: The use of Arcalyst will not be considered medically necessary for any of the following:
1. Dosing other than FDA approved dosing regimen. 2. In combination with other interleukin-1 inhibitor. 3. In combination with TNF inhibitor.

Required Medical Information: Genetic test identifying CIAS1 (Cold-Induced Autoinflammatory Syndrome 1) gene mutation (also know as NLRP3, NALP3 or PYPAF). Skin biopsy if performed. Serum amyloid, C-reactive protein. Extension of therapy will be medically necessary if documentation identifies symptom improvement or disease stability.

Age Restrictions: 12 years old and older

Prescriber Restrictions: Restricted to Rheumatologist, immunologist or dermatologist

Coverage Duration: Initial 6 month approval followed by an additional 6 months if medically necessary.

Other Criteria: -

Prior Authorization Group: AUBAGIO

Drug Names: AUBAGIO

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

Exclusion Criteria: Severe hepatic impairment

Required Medical Information: Diagnosis of relapsing form of multiple sclerosis, liver function test results, CBC results, patient progress notes.

Age Restrictions: 18 years and older

Prescriber Restrictions: Neurologist

Coverage Duration: 12 months

Other Criteria: -
Prior Authorization Group
AURYXIA

Drug Names
AURYXIA

Covered Uses
For the control of serum phosphorous levels in hyperphosphatemia adult patients with chronic kidney disease on dialysis

Exclusion Criteria
For the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. Prescription medications used as vitamin or mineral products, are excluded from Medicare Part D coverage. Auryxia is considered a vitamin or mineral product when used for the treatment of iron deficiency anemia. For the treatment of hyperphosphatemia in adult patients with chronic kidney disease NOT on dialysis

Required Medical Information
Documentation of diagnosis, current chart notes

Age Restrictions
- 

Prescriber Restrictions
Ordered by or Consult with nephrologist

Coverage Duration
12 months

Other Criteria
- 

Prior Authorization Group
B VS. D

Drug Names
ABELCET, ACETYLHYDROCO, ACYCOVIR SODIUM, ADRUCIL, ALBUTEROL SULFATE, AMBISOME, AMINOSYN II, AMINOSYN-PF, AMINOSYN-PF 7%, AMPHOTERICIN B, APREPITANT, AZATHIOPRINE, BENDEKA, BLEOMYCIN SULFATE, BROVANA, BUDESONIDE, CINACalcET HYDROCHLORIDE, CLADRIBINE, CROMOLYN SODIUM, CYCLOPHOSHAMIDE, CYCLOSPORINE, CYCLOSPORINE MODIFIED, CYTARABINE AQUEOUS, ENGEX-B, FLUOROURACIL, GANCICLOVIR, GENGRAF, GRANISETRON HCL, HEPATAMINE, INTRALIPID, IPATROPIUM BROMIDE, IPATROPIUM BROMIDE/ALBUT, LEVALBUTEROL, LEVALBUTEROL HCL, LEVALBUTEROL HYDROCHLORID, MYCOPHENOLATE MOFETIL, MYCOPHENOLIC ACID DR, NEBUPENT, NEPHRAMINE, NULOXIN, ONDANSETRON HCL, ONDANSETRON HYDROCHLORIDE, ONDANSETRON ODT, PERFOROMIST, PREMASOL, PROCALAMINE, PROGRAF, PROSOL, PULMOZYME, RAPAMUNE, RECOMBIVAX HB, SENSIPAR, SIMULATE, SIROLIMUS, TACROLIMUS, THYMOCLOBULIN, TOBRAMycin, TOBRAMycin SULFATE, TRAVASOL, TROPHAMINE, VARUBI, VINCBLASTINE SULFATE, VINCASAR PFS, VINCIRISTINE SULFATE, ZORTRESS

Covered Uses
NA

Exclusion Criteria
- 

Required Medical Information
- 

Age Restrictions
- 

Prescriber Restrictions
- 

Coverage Duration
NA

Other Criteria
- 

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<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>BENLYSTA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Names</strong></td>
<td>BENLYSTA</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Required Medical Information</strong></td>
<td>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</td>
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<tr>
<td><strong>Age Restrictions</strong></td>
<td>18 years old and older</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Rheumatologist</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>6 months initial, extension 12 months</td>
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<tr>
<td><strong>Other Criteria</strong></td>
<td>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)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>BIOLOGIC RESPONSE MODIFIERS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Names</strong></td>
<td>BAVENCIO, DAURISMO, FARYDAK, IBRANCE, IDHIFA, IMFINZI, KISQALI, KISQALI FEMARA 200 DOSE, KISQALI FEMARA 400 DOSE, KISQALI FEMARA 600 DOSE, LIBTAYO, LUMOXITI, LYNPARZA, MYLOTARG, NINLARO, OPDIVO, RUBRACA, TALZENNA, VELCADE, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, YERVOY, ZEJULA</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
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<td><strong>Exclusion Criteria</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Required Medical Information</strong></td>
<td>Documentation of diagnosis for use, current chart notes and any previous and concurrent therapies</td>
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<tr>
<td><strong>Age Restrictions</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Oncologist</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>12 months</td>
</tr>
<tr>
<td><strong>Other Criteria</strong></td>
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<tr>
<td>Prior Authorization Group</td>
<td>CESAMET</td>
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<tr>
<td>Drug Names</td>
<td>CESAMET</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All medically accepted indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Hypersensitivity to any cannabinoid</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Documentation that the member is receiving chemotherapy for the treatment of cancer and is experiencing nausea and vomiting. Previous antiemetic treatments that member has failed.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Ordered by or consult with an oncologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Member must have failed therapy with the following conventional antiemetic treatments: aprepitant or rolapitant in combination with ondansetron, or dolasetron, or granisetron.</td>
</tr>
</tbody>
</table>
### Prior Authorization Group
CIALIS FOR BPH

### Drug Names
CIALIS, TADALAFIL

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

### Exclusion Criteria
Concomitant use of nitrate-based drugs (nitroglycerin) for heart conditions, Hypersensitivity reaction to Cialis or Adcirca

### Required Medical Information
Cialis (tadalafil) 2.5mg or 5mg may be considered medically necessary when the following criteria are met. Enlarged prostate AND bothered by symptoms for at least 50 percent of the time over one month. Moderate to severe uncontrolled symptoms due to benign prostatic hyperplasia (BPH) with an American Urological Association Symptom Index (AUA-SI) greater than 8. (Symptoms include incomplete emptying, frequency, intermittency, urgency, weak stream, straining, nocturia.) Failure (defined less than 50 percent improvement of symptoms after 3 month trial), to the following two different combination therapies: alpha-blocker with an anticholinergic and alpha-blocker with a 5-alpha-reductase inhibitor, OR has a contraindication or are intolerant to all appropriate drug classes used to treat BPH. For continued therapy: must be a reduction in symptoms.

### Age Restrictions
18 years old and older

### Prescriber Restrictions
Restricted to urologists (or urology consult identified)

### Coverage Duration
Remainder of the contract year.

### Other Criteria
Will not be covered solely for: erectile dysfunction (ED) for standard plans, status post radical prostatectomy, in combination with other PDE 5 inhibitors or soley to reduce PSA level. The use of Cialis 2.5mg tablets will be approved for members with a creatinine clearance of 30 to 50mL/min or in patients that are unable to tolerate the 5mg dose

### Prior Authorization Group
CYCLOBENZAPRINE

### Drug Names
CYCLOBENZAPRINE HYDROCHLO

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

### Exclusion Criteria
- Documentation of indication of use. The prescriber must be aware that the medication poses a high risk for use in most patients 65 years of age or older. Documentation that the prescriber acknowledges that medication benefit outweigh potential risk in patients 65 years of age or older

### Required Medical Information
Prior authorization only applies to patient 65 years or older

### Age Restrictions
- 

### Prescriber Restrictions
- 

### Coverage Duration
12 months

### Other Criteria
For musculoskeletal pain, the patient must have a documented failure of metaxalone. For fibromyalgia, the patient must have documented failure of two of the following medications: duloxetine, gabapentin or Lyrica.
**Prior Authorization Group** | CYSTARAN  
**Drug Names** | CYSTARAN  
**Covered Uses** | All FDA-approved indications not otherwise excluded from Part D.  
**Exclusion Criteria** |  
**Required Medical Information** | Diagnosis of cystinosis with corneal crystal accumulation, Corneal cystine crystal score prior to start of therapy  
**Age Restrictions** |  
**Prescriber Restrictions** | Ophthalmologist  
**Coverage Duration** | 12 months  
**Other Criteria** | For continuation of therapy documentation must be provided identifying either a lack of increase or reduction in the corneal cystine crystal score.

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**Prior Authorization Group** | DARAPRIM  
**Drug Names** | DARAPRIM  
**Covered Uses** | All medically accepted indications not otherwise excluded from Part D  
**Exclusion Criteria** | Megaloblastic anemia due to folate deficiency  
**Required Medical Information** | Chart notes identifying Daraprim will be used for the prophylaxis or treatment of toxoplasmosis, prophylaxis or treatment of pneumocystis pneumonia (PCP) or prophylaxis or treatment of malaria  
**Age Restrictions** |  
**Prescriber Restrictions** |  
**Coverage Duration** | 12 months  
**Other Criteria** | For the prophylaxis of Toxoplasmosis, and prophylaxis or treatment of PCP -must have contraindication to the use of trimethoprim-sulfamethoxazole. For the prophylaxis or treatment of malaria must have failed therapy with, or have a contraindication to the use of atovaquone-proguanil and mefloquine.

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**Prior Authorization Group** | DIFICID  
**Drug Names** | DIFICID  
**Covered Uses** | All FDA-approved indications not otherwise excluded from Part D.  
**Exclusion Criteria** |  
**Required Medical Information** | Stool sample positive for clostridium difficile toxin.  
**Age Restrictions** | 18 years old and older  
**Prescriber Restrictions** | Restricted to Infectious Disease and gastroenterologist.  
**Coverage Duration** | 10 days  
**Other Criteria** | Failure of a 10-14 day course of treatment of metronidazole and oral vancomycin.  
(Recurrence of c. difficile AFTER treatment with vancomycin or metronidazole does not meet the criteria for failure of vancomycin or metronidazole.)
### Prior Authorization Group

- DRONABINOL

### Drug Names

- DRONABINOL

### Covered Uses

- All medically accepted indications not otherwise excluded from Part D.

### Exclusion Criteria

- Hypersensitivity to any cannabinoid

### Required Medical Information

- Documentation of diagnosis, and documentation of any previous therapies

### Age Restrictions

- For AIDS-associated loss of appetite, 18 years and older

### Prescriber Restrictions

- Coverage Duration

- 12 months

### Other Criteria

- For chemotherapy induced nausea and vomiting associated with cancer chemotherapy or for postoperative nausea and vomiting: member must have failed therapy with the following conventional antiemetic treatments: aprepitant or rolapitant in combination with ondansetron, or dolasetron, or granisetron. For AIDS-associated loss of appetite the member must have failed therapy with a trial of megestrol.
**Prior Authorization Group**: ENBREL

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

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

**Exclusion Criteria**

**Required Medical Information**

Psoriatic Arthritis: Documentation identifying number of tender and swollen joints, PE findings, diagnosis of psoriasis or family history (diagnosis in a 1st or 2nd degree relative) of psoriasis, previous and current therapies and responses. RA: chart notes identifying persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration. AS: Documented significant clinical symptoms such as those identified in the BASDAI greater than 4 (0-10). Psoriasis: For initial treatment, documentation of moderate to severe plaque psoriasis

**Age Restrictions**

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

**Prescriber Restrictions**

Restricted to rheumatologists or immunologists for members with arthropathies, dermatologists

**Coverage Duration**

12 months

**Other Criteria**

A. For moderate to severe active adult RA the following must be met: Failed to respond to 1 or more nonbiologic DMARDs, 1 of which is an adequate trial of a maximally tolerated dose of MTX. If the member has a contraindication or significant intolerance to methotrexate, the member must have failed to respond to an adequate trial of 1 other DMARD at a maximally tolerated dose for at least 3 months. B. For moderate to severe JIA as indicated by 4 affected joints with limitation of motion, pain, tenderness or both, or persistent symptoms, the following criteria must be met: Failure to respond to an adequate trial of one DMARD. C. For the treatment of moderate to severe psoriatic arthritis as indicated by 3 or more tender joints AND 3 or more swollen joints on 2 separate occasions at least 1 month apart, the following criteria must be met: Must have had an inadequate response to at least 1 NSAID, and Failed to respond to an adequate trial of at least 1 DMARD. D. Enbrel for plaque psoriasis will be considered medically necessary when ALL of the following criteria are met: Moderate to severe chronic plaque psoriasis or involvement of the palms, soles of feet, facial or genital regions. An appropriate treatment trial of at least one of the following agents was not effective: MTX, oral retinoids, cyclosporine. E: For AS:failure during a 3 month period of 1 NSAID at maximum tolerated dose and BASDAI greater than or equal to 4 and Failure of a 12 week trial of sulfasalazine at maximum tolerated dose in patients with persistent peripheral arthritis, no trial of DMARDS required for pure axial manifestations. Continued coverage for all indications will be based on significant symptom improvement.
Prior Authorization Group: EPIDIOLEX
Drug Names: EPIDIOLEX
Covered Uses: All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria: -
Required Medical Information: Documentation of diagnosis, current chart notes and any previous and concurrent therapies
Age Restrictions: 2 years and older
Prescriber Restrictions: Ordered by or Consult with neurologist
Coverage Duration: 12 months

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

**Drug Names**  
ESBRIET

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

**Exclusion Criteria**  
-

**Required Medical Information**  
Documented diagnosis of idiopathic pulmonary fibrosis (IPF), HRCT results identifying the presence of a usual interstitial pneumonia (UIP) pattern, Lung biopsy confirming UIP if available, PE findings and liver function tests.

**Age Restrictions**  
18 years and older

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

**Coverage Duration**  
6 months

**Other Criteria**  
Must have FVC greater than or equal to 50% of predicted and a carbon monoxide diffusing capacity of greater than or equal to 30% of predicted prior to start of therapy. Must rule out other causes of interstitial lung disease such as domestic and occupational environmental exposures, connective tissue disease and/or drug toxicity. LFT’s must be less than 5x ULN. For continuation of therapy documentation must identify improvement or maintenance of disease (less than a 10% decline in FVC).

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**Prior Authorization Group**  
FABRY DISEASE

**Drug Names**  
GALAFOLD

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

**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**  
-
<table>
<thead>
<tr>
<th><strong>Prior Authorization Group</strong></th>
<th>FENTANYL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Names</strong></td>
<td>FENTANYL CITRATE, FENTANYL CITRATE ORAL TRA, FENTORA</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Required Medical Information</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>Transmucosal solid dosage form restricted to 16 and older. All other forms restricted to 18 years and older.</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Restricted to oncologists and pain management specialists</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>Initial 3 months approval followed by 6 month intervals.</td>
</tr>
<tr>
<td><strong>Other Criteria</strong></td>
<td>Fentanyl oral transmucosal or buccal solid dosage forms require prior authorization (for all quantities) and may be considered medically necessary when all of the following criteria are met: 1. Immediate-release (short-acting) opioid drugs are ineffective supported by documentation of excessive rescue doses used. 2. Already receiving but tolerant to a chronic pain around-the-clock extended release formulation. (Opioid tolerant patients are those who are taking around-the-clock medicine consisting of at least 60mg oral morphine, 30mg oral oxycodone, 8mg of oral hydromorphone, or an equianalgesic dose of another opioid daily for one week or longer.)</td>
</tr>
</tbody>
</table>
**Prior Authorization Group**
FIRAZYR

**Drug Names**
FIRAZYR

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

**Exclusion Criteria**
- 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 Firazyr use: diminished symptoms, decreased severity of attack, reduced duration of attacks, and decreased hospitalizations when compared to previous therapies. Please provide date of last attack.

**Age Restrictions**
18 years old and older

**Prescriber Restrictions**
Allergist, immunologist, or hematologist

**Coverage Duration**
Three month intervals

**Other Criteria**
Not to be used in combination with Kalbitor or Berinert. Triggers (e.g. surgery, major dental work, etc.) of attacks have been prophylactically treated appropriately and HAE attacks persist OR contraindication (such as pregnancy or lactation) or severe intolerance to attenuated androgens (e.g. danazol). Member has been compliant with preventative therapy, therapy has been optimized, and HAE attacks persist.
<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>FIRDAPSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>FIRDAPSE</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Patients with a history of seizures or seizure disorder.</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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)).</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a neurologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>Initial coverage: 6 months Continued coverage: 12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>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.</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>FORTEO</td>
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<tr>
<td>Drug Names</td>
<td>FORTEO</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Forteo required information: Diagnosis of osteoporosis in Postmenopausal female or primary hypogonadal male at high risk of fracture. Glucocorticoid induced osteoporosis on a daily dose equivalent to 5mg or greater of prednisone for at least 3 months and at high risk for fracture. And one of the following: 1. The member has a BMD T-score of less than or equal to 2.5 at the hip, femoral neck or spine and has documented failure of an adequate trial of oral alendronate, or ibandronate unless the member has a contraindication or intolerance to bisphosphonates: or 2. New osteoporotic/fragility fracture despite an adequate trial of oral alendronate or risedronate. For continued therapy must demonstrate maintenance in BMD of the lumbar spine, femoral neck, or whole body</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>-</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>24 months</td>
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<tr>
<td>Other Criteria</td>
<td>Doses exceeding the FDA approved package labeling are not covered. Teriparatide is not a covered benefit in the following situations: prevention of osteoporosis in men and women, members with Paget's disease or unexplained elevations of alkaline phosphatase, members with a history of bone metastases, skeletal malignancies and/or metabolic bone disease other than osteoporosis, members with hypercalcemia, or in combination with a bisphosphonate. Teriparatide is not covered after two years of treatment.</td>
</tr>
</tbody>
</table>
Prior Authorization Group: GAUCHERS DISEASE
Drug Names: CEREZYME, MIGLUSTAT, VPRIV, ZAVESCA
Covered Uses: All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria: The use of these agents will not be considered medically necessary in the following situations: members with Type 2 or Type 3 Gaucher's Disease, asymptomatic Type 1 disease, carriers of Gaucher's Disease, combination use of any of these agents. Miglustat is not covered for severe disease (severe disease defined as a hemoglobin concentration below 9 g/dL or a platelet count below 50 x 10^9/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

GROWTH HORMONE THERAPY

Drug Names

HUMATROPE, HUMATROPE COMBO PACK, NORDITROPIN FLEXPRO

Covered Uses

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

Exclusion Criteria

GH will not be covered for the following: active malignant condition. If GHD results from an intracranial tumor, absence of tumor growth or tumor recurrence for at least 6 months prior to therapy initiation. GH is not indicated for treatment of wounds or burns. PWS with 1 or more risk factors including severe obesity, h/o respiratory impairment or sleep apnea, or unidentified respiratory infection. Catabolic illnesses or to improve muscle strength or exercise tolerability. Members w/ active proliferative or severe non-proliferative (preproliferative) diabetic retinopathy. Current or predicted ht without GH therapy greater than or equal to mid-parental height. Non-euthyroid state. Ext of therapy for children for GHD will not be covered if no further growth or mid-parental ht is achieved OR epiphyseal fusion is complete OR bone age indicates growth is complete OR renal transplant has occurred (for CRI) OR growth rate of 2cm/yr has not occurred.IGF-1 in combo with GH is not covered.

Required Medical Information

A.GHD: ht must be beneath 3rd percentile of normal or 2 SD below 50th percentile AND growth velocity must be less than 10th percentile of normal or greater than 2 SD below the mean AND lack of response to 2 separate GH provocative tests. B. Children with Turner Syndrome: present ht must be below the 5th percentile of normal OR ht greater than 2 SD below the mid-parental ht prediction or growth velocity less than 25% for bone age and bone age less than 14 years.C. Children w/ PWS: Severe hypotonia in neonates, followed by hyperphagia and obesity. D. ISS: in the presence of GH deficiency AND with open growth plates AND ht less than the 3rd percentile AND growth velocity less than 10th percentile.

Age Restrictions

Per package label

Prescriber Restrictions

Endocrinologists or Nephrologists

Coverage Duration

12 months

Other Criteria

-
<table>
<thead>
<tr>
<th><strong>Prior Authorization Group</strong></th>
<th>HEREDITARY ANGIOEDEMA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Names</strong></td>
<td>CINRYZE, RUCONEST</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Required Medical Information</strong></td>
<td>Diagnosis of hereditary angioedema (HAE) with lab data confirming diagnosis: a. C1-INH and serum complement factor 4 level below the reference range along with a serum C1q level within normal reference range, OR b. C1-INH level that is normal or elevated but dysfunctional, low C4 level and normal C1q level, OR c. Normal C1-INH with normal functional assay and normal C4 and C1q levels. Must have family history of HAE</td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>Cinryze-6 years and older, Ruconest-13 years and older</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Allergist, immunologist or hematologist</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>6 months initial, extension 12 months</td>
</tr>
<tr>
<td><strong>Other Criteria</strong></td>
<td>Documentation that triggers of attacks have been prophylactically treated appropriately with attenuated androgens, and aminocaproic acid or tranexamic acid and HAE attacks persist. Ruconest will only be approved for the treatment of acute attacks and for extensions of therapy documentation must identify decreased severity and duration of attacks and decreased hospitalization. Cinryze will only be approved for prophylaxis against HAE attacks and for extensions of therapy documentation must identify a decrease in hospitalizations or emergency room visits compared to previous therapy.</td>
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<thead>
<tr>
<th><strong>Prior Authorization Group</strong></th>
<th>HETLIOZ</th>
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<tbody>
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<td><strong>Drug Names</strong></td>
<td>HETLIOZ</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
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<tr>
<td><strong>Required Medical Information</strong></td>
<td>Documentation that the patient is totally blind. Diagnosis of Non-24-hour Sleep-Wake Disorder Circadian rhythm sleep-wake disorder, Non-24-hour sleep wake type or Circadian rhythm sleep disorder, free-running type. Sleep disturbance cannot be explained by other current sleep disorder, medical or neurological disorder, mental disorder, medication use of substance use disorder</td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>18 years old and older</td>
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<tr>
<td><strong>Prescriber Restrictions</strong></td>
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</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>3 months initial, extension 12 months</td>
</tr>
<tr>
<td><strong>Other Criteria</strong></td>
<td>Patient must have history of insomnia, excessive daytime sleepiness or both, which alternate with asymptomatic episodes.</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>HORMONAL ANTINEOPLASTIC AGENTS</td>
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</tr>
<tr>
<td>Drug Names</td>
<td>ERLEADA, YONSA</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Documentation of diagnosis, current chart notes and any previous and concurrent therapies</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>-</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Oncologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>-</td>
</tr>
</tbody>
</table>
**Prior Authorization Group**

**Drug Names**

HUMIRA, HUMIRA PEDIATRIC CROHNS D, HUMIRA PEN, HUMIRA PEN-CD/UC/HS START, HUMIRA PEN-PS/UV STARTER

**Covered Uses**

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

**Exclusion Criteria**

Frequency/dose not greater than 40mg every other week except for the initial 2-week induction period for Crohn's Disease or Ulcerative colitis and plaque psoriasis OR for rheumatoid arthritis after a failure of every other week dosing. For arthritis, Prior trial with mtx unless documentation of acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease. Chart notes including physical exam findings, number of swollen or tender joints, duration of morning stiffness, other symptoms, requested dose and frequency and expected duration of therapy. For Crohn's disease and Ulcerative colitis: response to or an intolerance to conventional therapy. Assessment of growth, nutrition, therapy-induced complications and functional ability. Clinical signs and symptoms such as frequency of stools, severity grade and frequency of abdominal pain, presence of an abdominal mass, extra-intestinal symptoms, prescription history, and current and past weights. For psoriasis: %BSA involvement current and with extension of therapy, previous and current therapies and responses. For a diagnosis of AS, chart notes including status of back pain and spinal mobility. For Psoriatic arthritis: chart notes including number of tender and swollen joints, previous therapies, diagnosis of psoriasis or family history (diagnosis in a first or second degree relative) of psoriasis.

**Age Restrictions**

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

**Prescriber Restrictions**

12 months

**Coverage Duration**

A. For moderate-severe active adult RA w/synovitis and AM stiffness of significant duration to inhibit ADLs, the following must be met: Failed to respond to 1 or more nonbiologic DMARDs, 1 of which is an adequate trial of max tolerated dose of MTX. If the member has contraindication or intolerance to MTX, then must have failed to respond to an adequate trial of 1 other DMARD at a maximally tolerated dose for at least 3 months. B. For moderate-severe JIA as indicated by 5 swollen joints and 3 or more joints w/limitation of motion, pain, tenderness or both, or persistent symptoms, the following must be met: Failed to respond to an adequate trial of 1 DMARD. C. For the trmt of moderate-severe PsA as indicated by 3 or more tender joints AND 3 or more swollen joints on 2 separate occasions at least 1 month apart, the following must be met: Must have had an inadequate response to 1 NSAID, and Failed to respond to an adequate trial of at least 1 DMARD. D. Humira for Plaque psoriasis will be considered when ALL of the following are met: Moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp. An appropriate trial was not effective or contraindicated with one of the following: MTX, oral retinoids, cyclosporine. E: For AS: failure during a 3 month period of 1 NSAID at max tolerated dose and BASDAI greater than or equal to 4, Failure of a 12 week trial of sulfasalazine at max tolerated
dose in patients with persistent peripheral arthritis, no trial of DMARDS required for pure axial manifestations. F. Criteria for confirmed Crohn's and UC: all of the following must be met: intolerance to 2 different drug classes (e.g. corticosteroids and immunomodulators such as AZA or 6-MP), clinical signs and symptoms such as frequent liquid stools greater than 4/day, presence of abdominal pain, need for opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss greater than 10%. Concomitant therapy with Rituxan, biologic or targeted therapies will not be covered. Continuation of therapy for all indications will require documentation of improvement of clinical signs and symptoms.

Prior Authorization Group
ILARIS

Drug Names
ILARIS

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

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

Required Medical Information
- Age Restrictions
  CAPS -4 years of age and greater, SJIA-2 years of age and greater
- Prescriber Restrictions
  Rheumatologist, immunologist or dermatologist
- Coverage Duration
  Initial 4 months with 12 month extensions
- Other Criteria
  For Systemic Juvenile Idiopathic Arthritis: Documentation must include failure or inadequate response to a 1 month trial of Kineret and a 12 week trial of Actemra. If chart notes identify intolerance, and/or clinical side effects, and/or contraindication to Kineret and Actemra, the following must be documented: Failed to respond to an adequate trial of maximally tolerated dose of methotrexate or leflunomide. For Cryopyrin-Associated Periodic Syndromes: failure or inadequate response to a 12 weeks trial of Kineret
Prior Authorization Group

IMMUNOGLOBULIN THERAPY

Drug Names

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

Covered Uses


Exclusion Criteria

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

Age Restrictions

Formulary ID 19583, Version 26
Updated 9/1/2019
### Prescriber Restrictions

**Coverage Duration**
Initial approval 3 months with extension of 6 month intervals.

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

### Prior Authorization Group

**Drug Names**
- CIPROFLOXACIN
- CIPROFLOXACIN I.V.-IN D5W
- GRANISETRON HCL
- LEVOFLOXACIN
- LEVOFLOXACIN IN D5W
- LINEZOLID
- ONDANSETRON HYDROCHLORIDE

### Coverage Duration

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

### Other Criteria

**Age Restrictions**

*Restricted to FDA approved package labeling age restrictions.*

**Prescriber Restrictions**

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

**Other Criteria**

These drugs may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug(s) to make the determination. Only covered for FDA approved indications not otherwise excluded from Part D. For continuation of the injectable version, chart notes must identify a better response than the oral product.

### Required Medical Information

Medical information identifying that the patient was unable to tolerate the oral preparation prior to initiation of the intravenous form of the medication. Medical information must include ONE of the following: For any medication under this prior authorization group including anti-emetics:

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

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.
### Prior Authorization Group

**Drug Names**
- ITRACONAZOLE

**Covered Uses**
All FDA-approved indications not otherwise excluded from Part D and the following:
- tinea corporis, cruris or pedis

**Exclusion Criteria**
- Congestive heart failure

**Required Medical Information**
For onychomycosis: Positive KOH test from a nail scraping or a positive pathogenic fungal culture documenting the presence of hyphae consistent with susceptible dermatophytes (tinea unguium). Member is non-immunocompromised (e.g. negative HIV status, not undergoing chemotherapy, not a transplant recipient). Identify location of onychomycosis (e.g. fingernails and/or toenails). For lung fungal infections, start date of itraconazole and: Fungal cultures identifying one of the following:
1. Blastomycosis
2. Histoplasmosis
3. Aspergillosis.

**Age Restrictions**
- 18 years old and older

**Prescriber Restrictions**
- -

**Coverage Duration**
- Onychomycosis-12 weeks, all other indications-12 months

**Other Criteria**
For onychomycosis infection: failure or contraindication to terbinafine. For aspergillosis fungal infection: failure or contraindication to amphotericin B therapy. For tinea corporis, cruris or pedis: failure or contraindication to ketoconazole cream and econazole cream. Combination therapy with more than one antifungal agent (terbinafine, itraconazole, ciclopirox) will not be covered.

### Prior Authorization Group

**Drug Names**
- JAKAFI

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

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

**Required Medical Information**
Documentation provided supporting the diagnosis of intermediate or high-risk myelofibrosis including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. Baseline Modified Myelofibrosis Symptom Assessment Form (mMFSAF) total symptom score. Prognostic factors based on the International Working Group Consensus Criteria: Age greater than 65 years old, White blood cell count greater than 25 x 10 to the 9th /L, Hemoglobin less than 10 g/dL, Peripheral blood blast greater than or equal to 1 percent, Positive for constitutional symptoms (e.g. fatigue, weight loss, night sweats, and bone pain). For continuation of therapy: decrease in symptoms vs baseline MFSAF total symptom score. For Polycythemia vera: documented diagnosis of polycythemia vera.

**Age Restrictions**
- 18 years old and older

**Prescriber Restrictions**
- Oncologists

**Coverage Duration**
- 12 months

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

<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>JYNARQUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>JYNARQUE</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>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.</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Ordered by or Consult with nephrologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>3 months. Extended authorizations limited to 6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>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.</td>
</tr>
</tbody>
</table>
**Prior Authorization Group**

**Drug Names**
KALYDECO

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

**Exclusion Criteria**
- 

**Required Medical Information**
Documentation of: Diagnosis of cystic fibrosis (CF). Identification that there is one mutation in the CFTR gene that is responsive to 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 Restrictions**
Pulmonologist

**Coverage Duration**
6 months

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

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**Prior Authorization Group**

**Drug Names**
KINASE INHIBITORS

AFINITOR, AFINITOR DISPERZ, ALECENSA, ALIQOPA, ALUNBRIG, BALVERSA, BOSULIF, BRAFTOVI, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ, COPiKTRA, COTELIC, ICLUSIG, IMATINIB MESYLATE, IMBRUVICA, INLYTA, IRESSA, LENVIMA 10 MG DAILY DOSE, LENVIMA 12MG DAILY DOSE, LENVIMA 14 MG DAILY DOSE, LENVIMA 18 MG DAILY DOSE, LENVIMA 20 MG DAILY DOSE, LENVIMA 24 MG DAILY DOSE, LENVIMA 4 MG DAILY DOSE, LENVIMA 8 MG DAILY DOSE, LORBRENA, MEKINIST, MEKTOVI, NERLYNX, NEXAVAR, PIQRAY 200MG DAILY DOSE, PIQRAY 250MG DAILY DOSE, PIQRAY 300MG DAILY DOSE, RYDAPT, SPRYCEL, STIVARGA, SUTENT, TAGRISSO, VITRAKVI, VIZIMPRO, XALKORI, XOSPATA, ZELBORAF, ZYKADIA

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

**Exclusion Criteria**
- 

**Required Medical Information**
Documentation of diagnosis, current chart notes and any previous and concurrent therapies

**Age Restrictions**
- 

**Prescriber Restrictions**
Oncologist, transplant specialist, neurologist, or hematologist

**Coverage Duration**
12 months

**Other Criteria**
-
<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>KORLYM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>KORLYM</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Endocrinologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>Initial 3 month approval, extensions 6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>For continuation of therapy there must be a decrease in the HbA1c level from baseline</td>
</tr>
</tbody>
</table>

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

**KYNAMRO**

**Drug Names**

**KYNAMRO**

**Covered Uses**

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

**Exclusion Criteria**

Moderate or severe hepatic impairment, or active liver disease, including unexplained persistent elevations of serum transaminases, known sensitivity to product components

**Required Medical Information**

Diagnosis of homozygous familial hypercholesterolemia. Baseline ALT, AST, alkaline phosphatase, and total bilirubin. Baseline cholesterol panel. Continuation of therapy will be considered if there is a decrease in LDL cholesterol from baseline

**Age Restrictions**

18 years old and older

**Prescriber Restrictions**

Cardiologist, Lipidologist or Endocrinologist

**Coverage Duration**

Initial approval 6 months, extensions up to 12 months

**Other Criteria**

Failure to achieve goal LDL-C despite a 1 month trial of a combination of two of the following: High-dose statin, Bile acid sequestrant or Zetia (ezetimibe). Patient must not be receiving LDL apheresis

---

**Prior Authorization Group**

**LAZANDA**

**Drug Names**

**LAZANDA**

**Covered Uses**

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

**Exclusion Criteria**

Management of acute or postoperative pain, including dental pain, or headache/migraine. Management of pain in patients who are non-opioid tolerant. Intolerance or hypersensitivity to fentanyl

**Required Medical Information**

Diagnosis of cancer. Documentation of intended use for breakthrough cancer pain. Documentation of current opioid use for one week or longer which equals or surpasses:

- 60 mg oral morphine/day
- 25 mcg transdermal fentanyl/hour
- 30 mg oral oxycodone/day
- 8 mg oral hydromorphone/day
- 25 mg oral oxymorphone/day
- or any equianalgesic dose of another opioid. Documentation of failure of greater than 1 immediate release opioid or contraindication to the use of oral immediate release products. Extension of therapy requires documentation of: continued benefit from therapy and optimized long-acting opioid therapy at maximum tolerated dose

**Age Restrictions**

18 years old and older

**Prescriber Restrictions**

Oncologist, Anesthesiologist, Hospice Palliative Care specialist, or pain management specialist

**Coverage Duration**

Initial 3 months approval followed by 6 months intervals

**Other Criteria**

Patients must: Remain on chronic long acting opioid therapy and continue to meet the definition of opioid tolerance while taking Lazanda and show ineffective relief from immediate-release opioids by excessive rescue doses despite optimal long-acting opioid therapy. Prescribers must enroll in the TIRF REMS Access program
<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>LETAIRIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>AMBRISENTAN, LETAIRIS</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Use in pregnancy or for the treatment of idiopathic pulmonary fibrosis. Coverage will not be provided for: more than 1 tablet per day, or for the treatment of digital ulcers or erectile dysfunction. Combination therapy with other PAH agents will not be covered for initial therapy</td>
</tr>
</tbody>
</table>

**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**

- 

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<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>LIDOCAINE PATCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>LIDOCAINE</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D and diabetic neuropathy</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Hypersensitivity to local anesthetics of the amide type (like prilocaine or bupivacaine).</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Documentation of diagnosis of post-herpetic neuralgia or diabetic neuropathy.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>-</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>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.</td>
</tr>
</tbody>
</table>
**Prior Authorization Group**

**Drug Names**

**Covered Uses**

**Exclusion Criteria**

**Required Medical Information**

**Age Restrictions**

**Prescriber Restrictions**

**Coverage Duration**

**Other Criteria**

LIDOCAINE TOPICAL

LIDOCAINE, LIDOCAINE HCL, LIDOCAINE HCL JELLY

All medically accepted indications not otherwise excluded from Part D

- 

Documentation of diagnosis for use

- 

- 

12 months

- 

Prior Authorization Group

**Drug Names**

**Covered Uses**

**Exclusion Criteria**

**Required Medical Information**

**Age Restrictions**

**Prescriber Restrictions**

**Coverage Duration**

**Other Criteria**

MAYZENT

MAYZENT

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

Patients who have a CYP2C9*3/*3 genotype, OR in the last 6 months, experienced once of the following: myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III/IV heart failure, OR have a history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block or sick sinus syndrome, unless the individual has a functioning pacemaker.

Documentation indicating the patient has a diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease.

18 years of age and older

Prescribed by, or in consultation with, a neurologist

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

Prior Authorization Group

**Drug Names**

**Covered Uses**

**Exclusion Criteria**

**Required Medical Information**

**Age Restrictions**

**Prescriber Restrictions**

**Coverage Duration**

**Other Criteria**

MEGESTROL

MEGESTROL ACETATE

All medically accepted indications not otherwise excluded from Part D

- 

Current chart notes and diagnosis of use

18 years old and older

- 

12 months

Non-FDA approved diagnosis will be evaluated according to the CMS medically accepted indications requirements in Chapter 6 of the Medicare Prescription Drug Benefit Manual
**Prior Authorization Group**

**Drug Names**

**Covered Uses**

**Exclusion Criteria**

**Required Medical Information**

**Age Restrictions**

**Prescriber Restrictions**

**Coverage Duration**

**Other Criteria**

MODAFINIL

ARMODAFINIL, MODAFINIL

All medically accepted indications not otherwise excluded from Part D

- 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

17 years old and older

- Ordered by or Consult with a Gastroenterologist, Hepatologist, or Hematologist

12 months

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

MULPLETA

MULPLETA

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

- Documentation that the patient has chronic hepatic disease, date of upcoming procedure, platelet count prior to the procedure

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

4 weeks
Prior Authorization Group: MYALEPT

Drug Names: MYALEPT

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

Exclusion Criteria: Hypersensitivity to metreleptin. General obesity not associated with congenital leptin deficiency.

Required Medical Information: Documentation of: Diagnosis (noting generalized/partial, and congenital/acquired), Serum leptin level, Baseline triglyceride level, Baseline HbA1c level, Baseline fasting glucose level, Patient's current weight.

Age Restrictions: -

Prescriber Restrictions: -

Coverage Duration: Initial approval 6 months, extensions 12 months

Other Criteria: To be eligible for approval of Myalept therapy the patient must NOT have any of the following: Partial lipodystrophy, HIV-related lipodystrophy, Nonalcoholic Steatohepatitis (NASH), History of positive anti-metreleptin antibodies, General obesity in absence of generalized lipodystrophy, Diabetes Mellitus in absence of generalized lipodystrophy, Or hypertriglyceridemia in absence of generalized lipodystrophy. AND to be eligible for approval of Myalept therapy the patient MUST have all of the following: Clinical lipodystrophy (i.e. loss/absence of subcutaneous fat, insulin resistance, hypertriglyceridemia), Pharmacologic treatment of hypertriglyceridemia has been maximized or cannot be tolerated, Insulin therapy for the treatment of hyperglycemia has been maximized. For continued therapy: Documentation of response to Myalept must be provided with each request for extension of therapy that identifies improvement in the HbA1c, triglycerides and fasting glucose from baseline.

Prior Authorization Group: NAGLAZYME

Drug Names: NAGLAZYME

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

Exclusion Criteria: The use of Naglazyme will not be considered medically necessary for the following situations:Dose and/or frequency outside of package labeling.

Required Medical Information: Naglazyme may be considered medically necessary if all of the following criteria are met:Documentation identifying diagnosis of MPS VI based on urine test identifying excess mucopolysaccharides AND enzyme assays testing a variety of cells or body fluids in culture for enzyme deficiency.12-minute walk test between 5 and 400 meters. Extension of therapy will be considered if documentation identifies continued benefit based on improvement vs baseline and continued stability of the 12-minute walk test.

Age Restrictions: -

Prescriber Restrictions: -

Coverage Duration: Initial approval 6 months, extensions 12 months

Other Criteria: -
<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>NATPARA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>NATPARA</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Endocrinologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>3 months initial, extension 12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>For extensions of therapy must maintain a corrected serum calcium concentration between 7.5 and 10.6 mg/dL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>NOXAFIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>NOXAFIL</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Documentation that member is at risk of developing invasive Aspergillus or Candida infection due to being severely immunocompromised (i.e. HSCT recipient with GVHD, hematologic malignancy with prolonged neutropenia from chemotherapy) or documentation of an oropharyngeal candidiasis infection</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>13 years and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>-</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>Oropharyngeal candidiasis-2 weeks, aspergillus prophylaxis-3 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>For aspergillus or candida prophylaxis must have failed therapy with or have a contraindication of voriconazole. For oropharyngeal candidiasis infection must have failed therapy with or have contraindication to fluconazole and voriconazole</td>
</tr>
</tbody>
</table>
### NUEDEXTA

**Prior Authorization Group** | NUEDEXTA  
--- | ---  
**Drug Names** | NUEDEXTA  
**Covered Uses** | All FDA-approved indications not otherwise excluded from Part D.  
**Exclusion Criteria** | Concomitant use with quinidine, quinine or mefloquine. Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reaction. Hypersensitivity to dextromethorphan. Use with MAOI or within 14 days of stopping an MAOI Prolonged QT interval. Congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. Complete AV block without implanted pacemaker, or patients at high risk of complete AV block. Concomitant use of drugs that both prolong QT interval and are metabolized by CYP2D6  
**Required Medical Information** | Diagnosis of pseudobulbar affect (PBA). Chart notes for the previous 3 months identifying the member’s frequency of laughing and crying episodes. Center of Neurologic Studies Liability Scale (CNS-LS) score of greater than 13  
**Age Restrictions** | 18 years old and older  
**Prescriber Restrictions** | -  
**Coverage Duration** | Initial approval 3 months, extensions 12 months  
**Other Criteria** | Extensions of therapy will be based on improvement in frequency of laughing and crying episodes and CNS-LS score from baseline

### NUPLAZID

**Prior Authorization Group** | NUPLAZID  
--- | ---  
**Drug Names** | NUPLAZID  
**Covered Uses** | All FDA-approved indications not otherwise excluded from Part D.  
**Exclusion Criteria** | -  
**Required Medical Information** | Documentation of a diagnosis of Parkinson's disease for at least one year and severity and frequency of hallucinations and/or delusions  
**Age Restrictions** | 18 years and older  
**Prescriber Restrictions** | -  
**Coverage Duration** | 12 months  
**Other Criteria** | Hallucinations and/or delusions must have started after the diagnosis of Parkinson's disease. Will not be covered for dementia-related psychosis
<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>ODOMZO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>ODOMZO</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Oncologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Basal cell carcinoma must have recurred following surgery or radiation therapy or the patient is not a candidate for surgery or radiation therapy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>OFEV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>OFEV</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Documented diagnosis of idiopathic pulmonary fibrosis (IPF), HRCT results identifying the presence of a usual interstitial pneumonia (UIP) pattern, Lung biopsy confirming UIP if available, PE findings and liver function tests. For continued therapy: clinical response to OFEV must be provided with each request for extension of therapy</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 year and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Ordered by, or by consult with, a pulmonologist.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Must have FVC greater than or equal to 50% of predicted and a carbon monoxide diffusing capacity of 30 to 70% of predicted prior to start of therapy. Must rule out other causes of interstitial lung disease such as domestic and occupational environmental exposures, connective tissue disease and /or drug toxicity. For documentation of therapy documentation must identify improvement or maintenance of disease (less than a 10% decline in FVC).</td>
</tr>
</tbody>
</table>
**Prior Authorization Group**

**Drug Names**

**Covered Uses**

All medically accepted indications not otherwise excluded from Part D

**Exclusion Criteria**

Pregnancy. Coverage will not be provided for the following: treatment of digital ulcers, or dosing exceeding FDA approved package label. Combination therapy with other PAH agents will not be covered for initial therapy.

**Required Medical Information**

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

**Age Restrictions**

18 years old and older

**Prescriber Restrictions**

Cardiologist or pulmonologist

**Coverage Duration**

Initial authorization will be limited to 3 months. Extension up to 12 months

**Other Criteria**

Documentation must include failure or inadequate response to an adequate trial of Letairis (for new starts only).

---

**Prior Authorization Group**

**Drug Names**

**Covered Uses**

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

**Exclusion Criteria**

- Chart notes identifying diagnosis of cystic fibrosis and test results identifying a homozygous F508del mutation in the CFTR gene. Baseline ppFEV1 results, BMI and number of pulmonary exacerbations in the past 6 months.

**Age Restrictions**

2 years old and older

**Prescriber Restrictions**

Pulmonologist

**Coverage Duration**

6 months

**Other Criteria**

For extension of therapy member must meet one of the following: 1. stabilization or improvement in ppFEV1 from baseline. 2. Increase in BMI from baseline. 3. Decrease in the number of pulmonary exacerbations from baseline.
Prior Authorization Group
PRALUENT

Drug Names
PRALUENT

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

Exclusion Criteria
Members has one of the following conditions: 1) Prior clinical atherosclerotic cardiovascular disease (ASCVD) (see Other Criteria), or 2) Heterozygous familial hypercholesterolemia (HeFH). For members with ASCVD at least one of the following is met: 1) Current LDL-C 70mg/dL or greater after 3 months of treatment with optimized lipid-lowering therapy (see Other Criteria), 2) Current LDL-C 70mg/dL or greater with contraindication (CI) to statin or intolerance to statin (see Other Criteria), 3) Currently LDL-C 70mg/dL or greater with CI to statin (see Other Criteria). For members with HeFH at least one of the following is met: 1) Current LDL-C 100mg/dL or greater after at least 3 months of treatment with optimized lipid-lowering therapy (see Other Criteria), 2) Current LDL-C 100mg/dL or greater with CI or intolerance to statin (see Other Criteria), 3) Current LDL-C 100mg/dL or greater and CI to statin (see Other Criteria). For continuation: Response to therapy as demonstrated by a reduction in LDL-C

Required Medical Information

Age Restrictions
18 years old and older

Prescriber Restrictions

Coverage Duration
12 months

Other Criteria
Clinical ASCVD defined as acute coronary syndromes, myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, or findings from a CT angiogram or catheterization consistent with clinical ASCVD. Diagnosis of HeFH must be confirmed by one of the following: 1) Genetic confirmation, 2) Simon-Broome Diagnostic criteria: total cholesterol greater than 290mg/dL or LDL-C greater than 190mg/dL plus tendon xanthomas in first or second degree relative, or 3) Dutch Lipid Clinic Network total score greater than 8 points. Diagnosis of HeFH must be confirmed by Lipidologist, Endocrinologist or Cardiologist specializing in lipid management. Optimized lipid lower treatment is defined as: 1) Atorvastatin 40mg or greater, or 2) Rosuvastatin 20mg or greater. Members with a history of intolerance to statin must meet one of the following: 1) Intolerable muscle pain persisting at least 2 weeks where pain resolves upon stopping statin. Must re-challenge with original statin or rosvastatin. 2) Statin-associated elevation in creatine kinase (CK) level greater than or equal to 5 times UL that resolves upon discontinuation of statin. 3) Statin-associated rhabdomyolysis. Contraindication to statin must be due to one of the following: 1) Active liver disease or unexplained persistent elevations in serum transaminases (3 times ULN), or 2) Women who are pregnant or may become pregnant, or 3) Nursing mothers. Starting dose will be 75mg every 2 weeks
Prior Authorization Group: PROMACTA
Drug Names: PROMACTA
Covered Uses: All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria: PROMACTA will not be covered under Part D if used in an attempt to normalize platelet counts.

Required Medical Information:
- Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin prior to initiation of PROMACTA, every 2 weeks during the dose adjustment phase and monthly following establishment of a stable dose. Documentation whether member has had a splenectomy. For Diagnosis of chronic immune idiopathic thrombocytopenia purpura and severe aplastic anemia: CBC with differential with Platelet count less than 30 x 10^9/L. Outcome and length of previous therapies such as IVIG, corticosteroids, cytotoxic therapies, danazol, and azathioprine. For thrombocytopenia in patients with chronic hepatitis C to allow initiation and maintenance of interferon-based therapy: Documentations that the patient is eligible to receive interferon-based therapy. CBC with differential with Platelet count less than 75 x 10^9/L. Outcomes of any previous therapies such as splenic artery embolization, splenectomy or TIPS.
- Age Restrictions
- Prescriber Restrictions: Hematologist and hepatologist
- Coverage Duration: Initial approval will be for 3 months. Extension of therapy up to one year.
- Other Criteria:
  - 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 400 x 10^9/L after 2 weeks of therapy at lowest FDA approved dose.
### Prior Authorization Group

**Drug Names**
- REMICADE

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

**Exclusion Criteria**
- No TB skin test result provided or TB infection has not been treated appropriately.
- Concomitant therapy with Rituxan and other DMARDs or biologic therapies other than MTX. Members with CHF with NYHA class III/IV at doses of greater than 5mg/kg.

### Required Medical Information

**RA:** persistent or recurrent symptoms with synovitis and AM stiffness of significant duration to inhibit ADLs. For continued therapy: Achieving ACR 20 response AND demonstrated beneficial response.

**B. PsA:** documentation at least 3 tender joints AND at least 3 swollen joints on 2 separate occasions at least 1 month apart. For RA and PsA: Continuation of tx requires a decrease in swollen or tender joints and duration of AM stiffness.

**C. Psoriasis:** documentation of severe chronic plaque psoriasis with 10% BSA involvement OR involvement of the palms, soles of feet and scalp causing functional disability. Continuation of therapy will require documentation of improved patient status in the monitoring parameters of the following: A significant improvement of clinical S/S of psoriasis (e.g. itching, redness, scaling, psoriatic BSA coverage) at 3 months. QOL assessments improved per pt and/or MD. D. AS: chart notes including status of back pain and spinal mobility and BASDAI greater than or equal to 4.

### Age Restrictions

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

### Prescriber Restrictions

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

### Coverage Duration

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

### Other Criteria

Must be screened for immunologic and infectious diseases including hepatitis and TB.

**A. RA:** Documentation must include failure or inadequate response to a 12week trial each of Humira and Enbrel and given in combination with at least 12.5mg/week of mtx or maximum dose tolerable for the patient, OR If chart notes identify intolerance, and/or clinical side effects, and/or contraindication to Enbrel and Humira, the following must be documented: Failed to respond to an adequate trial of maximally tolerated dose of mtx. (Failure is defined as ACR response less than 20.) If the member has a contraindication or significant intolerance to mtx, the member must have failed to respond for an adequate trial to at least one other nonbiologic DMARDs at a maximally tolerated dose.

**B. Crohn's Disease and UC:** Documentation must include failure or inadequate response to a 12week trial of Humira and one of the following: 1. Corticosteroids, OR 2. Anti-inflammatory aminosalicylates (e.g. sulfasalazine) OR if chart notes identify intolerance and/or clinical side effects and/or contraindication to Humira, a trial of both...
corticosteroids and anti-inflammatory aminosalicylates is required. For PsA, Plaque Psoriasis, and AS: Documentation must include failure or inadequate response to a 12-week trial each of Humira and Enbrel, OR if chart notes identify intolerance, and/or clinical side effects, and/or contraindication to Enbrel and Humira, the following must be documented: PsA: Failed to respond to an adequate trial of one DMARD.

Plaque Psoriasis: An appropriate treatment trial of two of the following agents was not effective: methotrexate, oral retinoids, cyclosporine. AS: Failure during a 3-month period of 1 NSAIDS at maximum tolerated dose and insufficient response to 1 local corticosteroid inj (peripheral arthritis), Failure of a 12-week trial of sulfasalazine at maximum tolerated dose in patients with persistent peripheral arthritis. No trial of DMARDS required for pure axial manifestations. Members with Wegener's granulomatosis prior to failure of at least two of the following agents: azathioprine, cyclophosphamide, glucocorticoids, MTX. For continuation of coverage: clinical failure or less than desired effect with Remicade and no clinical rationale provided for continuation of therapy.

<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>RIBAVIRIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>RIBASPHERE, RIBAVIRIN</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Contraindications for the use of ribavirin, including pregnancy, renal failure, hemoglobinopathies.</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>HCV RNA level and genotype</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>-</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>-</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>12 to 48 weeks for adults and 24 to 48 weeks for children based on genotype</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Will not be approved as monotherapy for the treatment of hepatitis C. Criteria will be applied consistent with current AASLD/IDSA guidance</td>
</tr>
<tr>
<td><strong>Prior Authorization Group</strong></td>
<td>SAMSCA</td>
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<tr>
<td><strong>Drug Names</strong></td>
<td>SAMSCA</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Required Medical Information</strong></td>
<td>Documentation of the following: Evaluated for factors contributing to hyponatremia. Euvolemic (no edema) hyponatremia with Syndrome of Inappropriate Antidiuretic Hormone (SIADH) OR hypervolemic (edema) hyponatremia with heart failure or cirrhosis. Serum sodium less than 125 mEq/L OR hyponatremic with a serum sodium greater than or equal to 125 mEq/L AND symptomatic AND unable to restrict fluid due to documented disorder or condition that would limit compliance with fluid restriction. Tolvaptan must be initiated, titrated, and re-initiated in a hospital setting until stable. Unless contraindicated: failure of fluid restriction, saline infusion, drug therapy and/or sodium restriction (if indicated) or removal of offending medication. For continuation of therapy: Continued necessity of tolvaptan vs. standard of care therapies. Continued benefit from tolvaptan with stabilization of serum sodium to normal limits.</td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>18 years old and older</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Endocrinologists, Nephrologists</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>Maximum of 30 days</td>
</tr>
<tr>
<td><strong>Other Criteria</strong></td>
<td>Patients with symptoms that may indicate liver injury should discontinue treatment with Samsca. Samsca should not be used longer than 30 days.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Prior Authorization Group</strong></th>
<th>SILDENAFIL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Names</strong></td>
<td>SILDENAFIL CITRATE</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>Combination therapy will not be covered for the treatment of digital ulcer or erectile dysfunction.</td>
</tr>
<tr>
<td><strong>Required Medical Information</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>18 years old and older</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Ordered by or Consult with pulmonologist or cardiologist</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>Initial approval 4 months, extensions 12 months</td>
</tr>
<tr>
<td><strong>Other Criteria</strong></td>
<td>-</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>SYLVANT</td>
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<tr>
<td>---------------------------</td>
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</tr>
<tr>
<td>Drug Names</td>
<td>SYLVANT</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Diagnosis of multicentric Castleman's disease confirmed by lymph node biopsy. Screening results for human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). CT or MRI result. Current chart notes identifying if peripheral lymphadenopathy, fever, or organomegaly are present.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Oncologist or hematologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>HIV and HHV-8 screening results must be negative. For continued therapy: Documentation of response to Sylvant must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Prior Authorization Group</th>
<th>TAKHZYRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>TAKHZYRO</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>12 years and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Allergist, immunologist, or hematologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>3 months. Extended authorizations limited to 6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Not to be used in combination with Cinryze, or Haegarda. Triggers (e.g. surgery, major dental work, etc.) of attacks have been prophylactically treated appropriately and HAE attacks persist OR contraindication (such as pregnancy or lactation).</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>TEGSEDI</td>
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<td>---------------------------</td>
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<tr>
<td>Drug Names</td>
<td>TEGSEDI</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
</tbody>
</table>
| 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   | Neurologist, immunologist, or physician who specializes in the treatment of amyloidosis |
| Coverage Duration         | 3 months. Extended authorizations limited to 6 months |
| Other Criteria            | For continuation of therapy, clinical documentation showing the patient has experienced a positive clinical response to Tegsedi (ie, improved neurologic impairment, motor function, cardiac function, quality of life assessment) must be identified. |

<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>TETRABENAZINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
<td>TETRABENAZINE</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Concomitant use with reserpine or use of reserpine within the past 20 days. Members with liver disease. Uncontrolled or untreated depression.</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Chart notes including: baseline and any subsequent total Chorea Score or the Unified Huntington's Disease Rating Scale (UHDRS), neurological exam, genetic testing confirming Huntington's disease. Documentation of functional disability due to chorea symptoms from Huntington's disease. For continuation of therapy, total Chorea Score improved at least 3.5 units since initiating tetrabenazine therapy or the chorea has significantly improved.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Restricted to neurologists</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>Initial approval for 3 months. Continuation of therapy six months.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>For doses above 50mg per day testing must be provided identifying patient is an extensive or intermediate metabolizer of CYP2D6</td>
</tr>
</tbody>
</table>
### TOBI PODHALER

**Drug Names**: TOBI PODHALER

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

**Exclusion Criteria**: Hypersensitivity to any aminoglycoside, Forced expiratory volume in 1 second less than 25% or greater than 80% of predicted normal range, Colonization with *Burkholderia cepacia*.

**Required Medical Information**: Diagnosis of cystic fibrosis, Positive sputum culture for *Pseudomonas aeruginosa*, Baseline 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.

### TRETINOINS

**Drug Names**: TRETINOIN

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

**Exclusion Criteria**: Cosmetic use including wrinkles.

**Required Medical Information**: The use of topical tretinoins may be considered medically necessary if all of the following criteria are met: Diagnosis of acne vulgaris, Subsequent requests will be considered if there is documentation of: Improvement in acne lesions.

**Age Restrictions**: 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.

### TRIENTINE

**Drug Names**: TRIENTINE HYDROCHLORIDE

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

**Exclusion Criteria**: -

**Required Medical Information**: Documentation of the diagnosis of Wilson’s disease, baseline free serum copper level and 24-hour copper excretion results.

**Age Restrictions**: 6 years and older

**Prescriber Restrictions**: -

**Coverage Duration**: Initial 6 month approval, extensions 12 months.

**Other Criteria**: Must have failed therapy with or have a contraindication to the use of Depen. For continuation of therapy there must be a decrease in free serum copper level and 24-hour copper excretion results from baseline.
Prior Authorization Group: TYSABRI
Drug Names: TYSABRI
Covered Uses: All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria:
- Patients who have or have had PML.
- Patients who have had a hypersensitivity reaction to Tysabri.
- Patients with significantly compromised immune function.
Required Medical Information:
- Multiple Sclerosis: Diagnosis of relapsing-remitting form of multiple sclerosis, neurology notes from the past 2 years and baseline MRI scan prior to initiation of Tysabri. For continuation of therapy-Chart notes identifying continued benefit with a decrease in number of relapses from baseline.
- Crohn’s Disease: Moderate to severe active Crohn’s disease confirmed by endoscopy or capsule endoscopy when appropriate. Documentation of active disease such as frequent liquid stools greater than 4 times/day, presence of abdominal pain, presence of abdominal mass, extra-intestinal symptoms, need for opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss greater than 10%. For continuation of therapy-Chart notes identifying response to Tysabri must be provided with each request for extension of therapy that identifies improvement in the clinical signs and symptoms described.
Age Restrictions: 18 years old and older
Prescriber Restrictions: Neurologist or gastroenterologist
Coverage Duration: Initial approval 3 months with extensions for 6 months
Other Criteria:
- Multiple Sclerosis: Documented failure or significant side effects to a trial of two of the following: Avonex, Copaxone or Tecfidera. Documented failure is defined as having two of the following: 1. Two relapses within the previous 12 months 2. MRI identifying lesion progression while on therapy 3. Documented worsening disability while on therapy.
- Crohn’s Disease: Documentation must include failure or inadequate response to a 12-week trial of Humira. OR if chart notes identify intolerance and/or clinical side effects and/or contraindication to Humira, a trial of one corticosteroid and one anti-inflammatory aminosalicylate is required. Tysabri may be covered under Medicare Part B or D depending upon the circumstances. When covered under Part B, Tysabri is not covered under Part D. Information may need to be submitted describing the use and setting of the drug to make the determination.
<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
<th>UPTRA VI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Names</td>
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</tr>
<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Pulmonologist or Cardiologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Combination therapy with other PAH agents will not be covered for initial therapy</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Prior Authorization Group</th>
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</tr>
<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>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</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Oncologists and Dermatologists</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>Initial 3 month approval, followed by extensions up to 12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>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</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>VENTAVIS</td>
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<tr>
<td>Required Medical Information</td>
<td>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.</td>
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<tr>
<td>Prescriber Restrictions</td>
<td>Ordered by or Consult with pulmonologist or cardiologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>Remainder of contract year</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>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.</td>
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<th>Prior Authorization Group</th>
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<td>Exclusion Criteria</td>
<td>-</td>
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<tr>
<td>Required Medical Information</td>
<td>Documentation of diagnosis and previous therapies</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years and older</td>
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<td>Prescriber Restrictions</td>
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</tr>
<tr>
<td>Coverage Duration</td>
<td>12 months</td>
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<tr>
<td>Other Criteria</td>
<td>Must be used for the treatment of schizophrenia or Bipolar I disorder. Must have documentation of failure or significant intolerance to a trial of aripiprazole or quetiapine</td>
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<tr>
<td>Prior Authorization Group</td>
<td>VYNAQEL</td>
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<tr>
<td>Exclusion Criteria</td>
<td>-</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>Documentation indicating the patient has wild type or hereditary transthyretin amyloid cardiomyopathy</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>18 years of age and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Neurologist, cardiologist, or physician who specializes in the treatment of amyloidosis</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>3 months. Extended authorizations limited to 6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>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.</td>
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<thead>
<tr>
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<tr>
<td>Covered Uses</td>
<td>All FDA-approved indications not otherwise excluded from Part D.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Will not be covered for prophylactic use or diverticular disease.</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>For diagnosis of active non-invasive travelers diarrhea (TD): Moderate to severe distressing symptoms of travelers diarrhea are present and proven or strongly suspected to be caused by Escherichia coli based upon symptoms and travel destination. (When culture and susceptibility information are available, culture must identify E. coli and susceptible to rifaximin). For diagnosis of hepatic encephalopathy (HE) and Irritable Bowel Syndrome with Diarrhea (IBS-D): current chart notes, current and previous therapies.</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>12 years old and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>-</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>TD=3 days, HE=6 months, all other indications=6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Prior Authorization Group
**XOLAIR**

### Drug Names
**XOLAIR**

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

### Exclusion Criteria
- 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

### Required Medical Information
- For asthma: documented evidence of reversible airway disease, IgE level, test results identifying allergic sensitivity to perennial aeroallergens, previous and current therapy.
- For Chronic idiopathic urticaria (CIU): Duration of urticaria, previous and current therapy

### Age Restrictions
- Asthma: 6 years and older, CIU: 12 years and older

### Prescriber Restrictions
- Age Restrictions
- Prescription Restrictions

### Coverage Duration
- Initial approval: 3 months, extensions: 12 months
- Other Criteria: For asthma: member experiencing poor asthma control despite the use of the maximally tolerated dose of a medium to high dose inhaled corticosteroid in combination with a long-acting beta2 agonist or leukotriene inhibitor or theophylline unless contraindicated, IgE level must be between 30 and 1300 IU/ml. For CIU: Urticaria must be present for at least 6 weeks and other causes such as occupational, food, medication, etc. must have been ruled out, must have failed a minimum of a 2 week trial of the maximally tolerated dose of a potent H1 antihistamine in combination with a H2 antihistamine, a systemic corticosteroid or leukotriene receptor antagonist unless contraindicated

### Prior Authorization Group
**XYREM**

### Drug Names
**XYREM**

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

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

### Age Restrictions
- 18 years old and older

### Prescriber Restrictions
- Age Restrictions
- Prescription Restrictions

### Coverage Duration
- Initial approval: up to 3 months. Continued therapy: 6 months
- Other Criteria: Documented intolerance, contraindication, or failure of a 1 month trial of the following: For excessive daytime sleepiness (EDS), modafinil 200mg daily or armodafinil 150mg daily, AND formulary methylphenidate product.
Prior Authorization Group: ZORB fertile
Drug Names: ZORB fertile
Covered Uses: All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria: Active neoplasia. Acute respiratory failure. Acute critical illness due to complications following open heart or abdominal surgery.
Required Medical Information: Documentation that all of the following are met for Short Bowel Syndrome: Surgical resection of small bowel, congenital defect or disease-related loss of absorption. Patient is dependent on parenteral nutritional support and continues to lose weight. Documentation of weight loss or nutritional depletion on current therapies.
Age Restrictions: 18 years old and older
Prescriber Restrictions: Gastroenterologist
Coverage Duration: 4 weeks
Other Criteria: -