

## Medications Requiring Prior Authorization

Effective: January 1, 2025

The following list outlines medications that require review by the clinical pharmacist, and in some cases, a FirstCarolinaCare medical director. If your doctor asks for coverage of a drug that requires prior authorization, he or she must provide documentation to meet criteria for that particular medication. Providers must request prior authorization from FirstCarolinaCare for drugs on this list.

This list is subject to change.

To request a written copy of the coverage criteria, please contact FirstCarolinaCare Member Services at (855) 291-9336 for TTY users, 711, 8 a.m. to 8 p.m., local time, seven days a week. From April 1 – September 30 voicemail will be used on weekends and holidays.

FirstCarolinaCare Insurance Company's plans are HMO and PPO plans with a Medicare contract. Enrollment in a FirstCarolinaCare Insurance Company plan depends on contract renewal.

This information is not a complete description of benefits. Contact the plan for more information. Limitations, copayments and restrictions may apply. Benefits and copayments/co-insurance may change on January 1 of each year.

This information is available for free in other languages. Please contact our Member Services number at (855) 291-9336 for additional information. (TTY users should call 711.) Hours are from 8 a.m. – 8 p.m., local time, seven days a week. From April 1 – September 30, voicemail will be used on weekends and holidays.

Esta información está disponible sin cargo en otros idiomas. Para obtener información adicional, llame al Departamento de Servicios para los Miembros al (855) 291-9336. (Los usuarios de TTY deben llamar al 711). Nuestro horario de atención es de 8:00 a.m. a 8:00 p.m., horario local, los 7 días de la semana. Desde el 1.º de abril hasta el 30 de septiembre, puede dejar un mensaje de voz los fines de semana y feriados.

# AAT DEFICIENCY

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## Products Affected

- Aralast Np INJ 1000MG
- Glassia
- Prolastin-c INJ 1000MG/20ML
- Zemaira INJ 1000MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Doc of high-risk phenotype (e.g. PIZZ, PIZ(Null), PI(Null)(Null), plasma AAT level below 11 Micromol/L (corresponding to 80mg/DL) FEV1 greater than or equal to 35%
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Subject to BvD decision. Coverage is limited to a dosage of 60mg/kg weekly.

# ABELCET

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## Products Affected

- Abelcet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Invasive Aspergillosis, Blastomycosis, Candidiasis, Cryptococcosis, Leishmaniasis, Systemic Mycosis: in patients refractory to or intolerant of conventional Amphotericin B therapy, Pulmonary aspergillosis: chronic (cavitary or necrotizing) salvage therapy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	Subject to BvD decision.

# ACTEMRA

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## Products Affected

- Actemra INJ 162MG/0.9ML
- Actemra Actpen

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# ADALIMUMAB

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## Products Affected

- Adalimumab-adaz
- Adalimumab-adbm INJ 40MG/0.4ML
- Adalimumab-adbm Starter Package For Crohns Disease/uc/hs
- Adalimumab-adbm Starter Package For Psoriasis/uveitis
- Amjevita INJ 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML, 80MG/0.8ML
- Hadlima
- Hadlima Pushtouch

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# ADEMPAS

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## Products Affected

- Adempas

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Patients with severe hepatic disease, creatinine clearance less than 15mL/min or on dialysis, pregnant patients
<b>Required Medical Information</b>	Documentation of results of acute vasoreactivity testing.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# AIMOVIG

## Products Affected

- Aimovig

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Concomitant use with another Calcitonin Gene-Related Peptide (CGRP) Inhibitor.
<b>Required Medical Information</b>	Episodic Migraines (EM): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. Two of the following (CM): Trial and failure, contraindication, or intolerance (after at least a two month trial) to: amitriptyline or venlafaxine, b) Trial and failure, contraindication, or intolerance (after at least a two month trial) to: divalproex sodium or topiramate, or c) Trial and failure, contraindication, or intolerance (after at least a two month trial) to: one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol. Medication will not be used in combination with another injectable CGRP inhibitor.
<b>Age Restrictions</b>	EM, CM (initial): 18 years or older
<b>Prescriber Restrictions</b>	Neurologist, Headache Specialist, or Pain Specialist.
<b>Coverage Duration</b>	EM, CM (Initial): 6 months. EM, CM (Reauth): 12 months.
<b>Other Criteria</b>	EM, CM (Reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications (e.g. non-steroidal anti-inflammatory drugs [NSAIDs], triptans) has decreased since the start of CGRP therapy. CM (Reauth): Patient continues to be monitored for medication overuse headache.

Formulary ID: 25411, Version: 10, Effective Date: 01/01/2025

Last Updated: 10/10/2024

# AMBISOME

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## Products Affected

- Amphotericin B Liposome

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	Subject to BvD decision.



# AMBRISENTAN

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## Products Affected

- Ambrisentan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Severe hepatic disease, severe anemia, pregnant patients
<b>Required Medical Information</b>	Documented previous failure of or contraindication to a generic formulary CCB if testing reveals vasoactivity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# AMITRIPTYLINE

## Products Affected

- Amitriptyline Hcl TABS 150MG, 25MG, 75MG
- Amitriptyline Hydrochloride TABS 100MG, 10MG, 50MG
- Perphenazine/amitriptyline

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Depression: Trial with at least one formulary antidepressant. Chronic Pain: Trial with duloxetine or NSAID. Fibromyalgia: Trial with duloxetine, gabapentin, or pregabalin. IBS: Trial and failure of any two of the following: laxatives, loperamide, or anti-spasmodic agents. Post-herpetic Neuralgia: Trial with gabapentin or pregabalin. Headache: Trial with NSAID
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Provider must submit attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older. The drug is being prescribed for a medically accepted indication AND the Prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) and will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the patient.

# ANTIEMETIC THERAPIES

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## Products Affected

- Aprepitant CAPS
- Emend SUSR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chemotherapy-induced nausea and vomiting, due to highly emetogenic chemotherapy, including high-dose cisplatin, prophylaxis or chemotherapy-induced nausea and vomiting, due to moderately emetogenic chemotherapy, prophylaxis, or prevention of postoperative nausea and vomiting
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Subject to BvD decision.

# APOKYN

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## Products Affected

- Apomorphine Hydrochloride INJ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Concomitantly on a 5HT3 antagonist
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# ARANESP

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## Products Affected

- Aranesp Albumin Free INJ  
100MCG/0.5ML, 100MCG/ML,  
10MCG/0.4ML, 150MCG/0.3ML,  
200MCG/0.4ML, 200MCG/ML,  
25MCG/0.42ML, 25MCG/ML,  
300MCG/0.6ML, 40MCG/0.4ML,  
40MCG/ML, 500MCG/ML,  
60MCG/0.3ML, 60MCG/ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Adequate iron stores shown by Serum Iron and Serum Ferritin within normal range
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Subject to BvD decision.

# ARCALYST

## Products Affected

- Arcalyst

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Discontinuation with serious infections, concurrent use of TNFS (increased infection risk), Latent TB
<b>Required Medical Information</b>	Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic. Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (Initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone).
<b>Age Restrictions</b>	CAPS, FCAS, MWS: 12 years or older.
<b>Prescriber Restrictions</b>	Rheumatologist, Dermatologist, Immunologist, or Cardiologist
<b>Coverage Duration</b>	Initial: 4 months. 2nd Auth: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	N/A

Formulary ID: 25411, Version: 10, Effective Date: 01/01/2025

Last Updated: 10/10/2024

# ARIKAYCE

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## Products Affected

- Arikayce

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Mycobacterium avium complex (MAC) lung disease: Diagnosis of Mycobacterium avium complex (MAC) lung disease. Used as part of a combination antibacterial drug regimen. Used in patients who do not achieve at least two negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g., a macrolide, a rifamycin, ethambutol, etc).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist or pulmonologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# BERINERT

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## Products Affected

- Berinert

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Hereditary Angioedema (HAE) confirmed using Serum Complement Factor 4 (C4), CI Inhibitor (C1NH) Antigenic, and C1NH Functional levels (if available) taken at different times (second test confirms diagnosis)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Allergist, Immunologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A



# BESREMI

## Products Affected

- Besremi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of polycythemia vera as confirmed by all of the following: 1) One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women, or c) Increased red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. Both of the following: 1) Trial and failure, contraindication or intolerance (TF/C/I) to hydroxyurea, AND 2) TF/C/I to one of the following: Interferon alfa (e.g., Intron A) or Pegasys (peginterferon alfa 2a).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy.

# BRONCHITOL

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## Products Affected

- Bronchitol

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cystic Fibrosis (CF) (initial): Diagnosis of CF. Patient has passed the Bronchitol Tolerance Test (BTT).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy as evidenced by improvement from baseline in FEV1

# CABLIVI

## Products Affected

- Cablivi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acquired Thrombotic Thrombocytopenic Purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) Both of the following: Patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hematologist
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	N/A

# CARBAGLU

## Products Affected

- Carglumic Acid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency: diagnosis of hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase confirmed by enzyme analysis or DNA mutation analysis. Patients who do not have enzyme analysis or DNA mutation analysis results can be approved for a one month trial pending results. Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA): diagnosis of hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# CAYSTON

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## Products Affected

- Cayston

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Cystic Fibrosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist or Infectious Disease Specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# CERDELGA

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## Products Affected

- Cerdelga

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	CYP2D6 phenotype determination testing. Diagnosis of non neuropathic (Type 1) Gauchers Disease
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Physician who specializes in the treatment of Gauchers Disease
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# CHOLBAM

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## Products Affected

- Cholbam

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of bile acid synthesis defect due to single enzyme defect or disorder of peroxisomal function, with liver disease manifestations, steatorrhea, or complications due to decreased absorption of fat soluble vitamins
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	N/A

# CIMZIA

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## Products Affected

- Cimzia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review



# CINRYZE

## Products Affected

- Cinryze

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis (labs on two separate dates) based on evidence of a normal C1 level and a low C4 level (C4 less than 14mg/dL, normal range 14-40 mg/dL, or C4 below the lower limit of normal as defined by the laboratory performing the test) plus: a low C1 Inhibitor (C1INH) antigenic level (C1INH less than 19 mg/dL normal range 19-37 mg/dL, or C1INH antigenic level below the lower limit of normal as defined by the laboratory performing the test) or a normal C1INH antigenic level (C1INH greater than 18mg/dL) and a low C1INH functional level (functional C1INH less than 50%, or below the lower limit of normal as defined by the laboratory performing the test)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Allergist, Immunologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# COSENTYX

## Products Affected

- Cosentyx INJ 150MG/ML, 75MG/0.5ML
- Cosentyx Sensoready Pen

- Cosentyx Unoready

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Ankylosing Spondylitis (AS): Diagnosis of AS with a minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) at maximally indicated doses. Enthesitis-Related Arthritis (ERA): Diagnosis of ERA with TF/C/I to TWO non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, meloxicam, naproxen). Non-Radiologic Axial Spondyloarthritis (NR-AXSPA): Diagnosis of NR-AXSPA. Patient has signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.), AND a minimum duration of one month trial/failure, contraindication, or intolerance to two nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) at maximally indicated doses. Psoriasis (PSO): Diagnosis of moderate to severe plaque psoriasis. Documentation that the patient has chronic moderate or severe plaque psoriasis with One of the following: Greater than or equal to 3% body surface area involvement, Severe scalp psoriasis, Palmoplantar (i.e., palms, soles), facial, or genital involvement, AND Minimum duration of a 4-week TF/C/I to one of the following topical therapies: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar. Psoriatic Arthritis (PSA): Diagnosis of active PSA. with One of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail involvement

Formulary ID: 25411, Version: 10, Effective Date: 01/01/2025

Last Updated: 10/10/2024

<b>Age Restrictions</b>	(ERA): 4 years or older. (PSA): 2 years or older. (PSO): 6 years or older. All other indications: 18 years or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Rheumatologist or Dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	(Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline.

# CRESEMBA

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## Products Affected

- Cresemba CAPS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Concomitant use with CYP3A4 inhibitors or inducers
<b>Required Medical Information</b>	Documented Diagnosis of Invasive Aspergillosis with trial, failure, contraindication, or intolerance to voriconazole or diagnosis of invasive mucormycosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Infectious Disease Specialist
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	N/A

# CRINONE

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## Products Affected

- Crinone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	All indications: excluded if for fertility uses.
<b>Required Medical Information</b>	Secondary Amenorrhea: Diagnosis of Secondary Amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# CYCLOBENZAPRINE

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## Products Affected

- Cyclobenzaprine Hydrochloride TABS  
10MG, 5MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# CYSTADROPS

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## Products Affected

- Cystadrops

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cystinosis: Diagnosis of Cystinosis, confirmed by elevated Leukocyte Cystine Levels (LCL), genetic analysis of the CTNS Gene or Corneal Cystine Crystal Accumulation
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# CYSTAGON

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## Products Affected

- Cystagon

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Nephropathic Cystinosis confirmed by the presence of increased Cystine concentration in Leukocytes or by DNA testing
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A



# CYSTARAN

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## Products Affected

- Cystaran

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Corneal Cysteine Crystal Accumulation Cystinosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to Cystaran therapy

# DALFAMPRIDINE

## Products Affected

- Dalfampridine Er

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Seizures, renal impairment with a CrCL less than 50 mL/min or wheelchair bound
<b>Required Medical Information</b>	Baseline Timed 25-foot walk completed within 8-45 seconds, patient must be currently ambulatory. Continuation approval based on results of timed 25-foot walk or statement of clinical improvement.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 12 months (based on therapeutic response)
<b>Other Criteria</b>	Pt must be ambulatory with no history of seizures

# DEFERASIROX

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## Products Affected

- Deferasirox TBSO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# DIACOMIT

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## Products Affected

- Diacomit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of seizures associated with Dravet Syndrome (DS). Used in combination with clobazam.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy

# DOPTelet

## Products Affected

- Doptelet

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Thrombocytopenia Prior to Planned Procedure (TPPP): Diagnosis of Thrombocytopenia. Patient has chronic liver disease and is scheduled to undergo a procedure. Baseline platelet count is less than 50,000/MCL. Chronic Immune Thrombocytopenia (ITP): Diagnosis of Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP) or Relapsed/Refractory ITP. Baseline platelet count is less than 30,000/MCL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids, immunoglobulins, splenectomy, or Rituxan (rituximab). Patient's degree of Thrombocytopenia and clinical condition increase the risk of bleeding.
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	TPPP: 1 month. ITP: 12 months
<b>Other Criteria</b>	ITP (Reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.

# DOXERCALCIFEROL

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## Products Affected

- Doxercalciferol CAPS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Doc Secondary Hyperparathyroidism and Stage 3, 4, or 5 CKD and trial and failure, intolerance, or contraindication to calcitriol or paricalcitol.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist or Nephrologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# DUPIXENT

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## Products Affected

- Dupixent

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# EMGALITY

## Products Affected

- Emgality

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months. EM, CM (120 mg/mL strength only) (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to amitriptyline or venlafaxine, OR patient has a contraindication to both amitriptyline and venlafaxine, b) History of failure (after at least a two month trial) or intolerance to divalproex sodium or topiramate, OR patient has a contraindication to both divalproex sodium and topiramate, c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, or d) History of failure (after at least a two month trial) or intolerance to candesartan, OR patient has a contraindication to candesartan. All Indications (initial): Medication will not be used in combination with another injectable CGRP inhibitor.</p>
<b>Age Restrictions</b>	ECH, MP (initial): 18 years or older.
<b>Prescriber Restrictions</b>	Neurologist, Headache Specialist, Pain Specialist

Formulary ID: 25411, Version: 10, Effective Date: 01/01/2025

Last Updated: 10/10/2024



<b>Coverage Duration</b>	ALL indications (Initial): 6 months. All indications (Reauth): 12 months.
<b>Other Criteria</b>	EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. All Indications (reauthorization): Medication will not be used in combination with another injectable CGRP inhibitor.

# ENBREL

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## Products Affected

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini
- Enbrel Sureclick

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# EPCLUSA

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## Products Affected

- Epclusa

- Sofosbuvir/velpatasvir

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Epclusa (Sofosbuvir-Velpatasvir) will not be covered for patients that are requesting Epclusa (Sofosbuvir-Velpatasvir) in combination with another HCV direct acting antiviral agent
<b>Required Medical Information</b>	Sub of medical records doc a diagnosis of Chronic Hep C Virus. Criteria will be applied consistent with current AASLD-IDSA guidance.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hepatologist, Gastroenterologist, Infectious Disease Specialist, HIV Specialist
<b>Coverage Duration</b>	Approval period will be consistent with current AASLD/IDSA guidelines
<b>Other Criteria</b>	N/A

# EPIDIOLEX

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## Products Affected

- Epidiolex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Lennox-Gastaut Syndrome (LGS): Diagnosis of seizures associated with LGS. Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g. topiramate, lamotrigine, valproate). Dravet Syndrome (DS): Diagnosis of seizures associated with DS and trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g. topiramate, clobazam, valproate).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy

# EPOETIN

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## Products Affected

- Epogen INJ 10000UNIT/ML, 20000UNIT/ML, 2000UNIT/ML, 3000UNIT/ML, 4000UNIT/ML
- Procrit
- Retacrit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Adequate iron stores shown by Serum Iron and Serum Ferritin within normal range
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Subject to BvD decision.

# ESBRIET

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## Products Affected

- Pirfenidone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Idiopathic Pulm Fibrosis. Documented baseline liver function tests.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Pirfenidone will have MDL of 270 caps per 30 days.

# FINTEPLA

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## Products Affected

- Fintepla

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Dravet Syndrome: Diagnosis of Dravet Syndrome. Documented trial and failure, contraindication, or intolerance to at least one formulary generic anticonvulsant (e.g. valproate, valproic acid, clobazam, topiramate). Lennox-Gastaut Syndrome: Diagnosis of seizures associated with Lennox-Gastaut syndrome.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# FORTEO

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## Products Affected

- Forteo INJ 600MCG/2.4ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review



# GALAFOLD

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## Products Affected

- Galafold

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Fabry Disease with an amendable GLA variant
<b>Age Restrictions</b>	16 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months.
<b>Other Criteria</b>	FD (Reauth): Documentation of positive clinical response to Galafold therapy

# GATTEX

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## Products Affected

- Gattex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Short Bowel Syndrome with dependence on parenteral support for at least 12 months
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 6 months.
<b>Other Criteria</b>	Reauth: Documentation that the member has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy

# GLUCAGON-LIKE PEPTIDE-1 RECEPTOR (GLP-1) AGONIST DRUGS

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## Products Affected

- Mounjaro
- Ozempic INJ 2MG/3ML, 4MG/3ML, 8MG/3ML
- Rybelsus
- Trulicity

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: 1. A1C greater than or equal to 6.5%, 2. Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, 3. 2-hour plasma glucose (PG) greater than or equal to 200mg/dL during oral glucose tolerance test, OR For patients requiring ongoing treatment for T2DM, submission of medical records (e.g., chart notes) confirming diagnosis of T2DM.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months if the patient demonstrates a positive clinical response
Other Criteria	N/A

# GROWTH HORMONE

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## Products Affected

- Norditropin Flexpro
- Omnitrope
- Serostim INJ 4MG, 5MG, 6MG
- Somavert

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	GH Simulation tests, HT
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist, Oncologist, Infectious Disease Specialist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A

# HAEGARDA

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## Products Affected

- Haegarda

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Hereditary Angioedema (HAE) confirmed using Serum Complement Factor 4 (C4), CI Inhibitor (C1NH) Antigenic, and C1NH Functional levels (if available) taken at different times (second test confirms diagnosis)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Allergist, Immunologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# HARVONI

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## Products Affected

- Harvoni PACK
- Harvoni TABS 90MG; 400MG
- Ledipasvir/sofosbuvir

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Chronic Hepatitis C Virus Genotype 1a, 1b, 4, 5, or 6 including patients with decompensated liver disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist, Infectious Disease Specialist, Hepatologist
<b>Coverage Duration</b>	Coverage duration will follow recommendation set forth by the AASLD
<b>Other Criteria</b>	N/A

# HETLIOZ

## Products Affected

- Hetlloz Lq

- Tasimelteon

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome), AND 2) patient is totally blind (has no light perception). Smith-Magenis Syndrome (SMS) (initial): Diagnosis of Smith-Magenis Syndrome (SMS). Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 12 months.
<b>Other Criteria</b>	N/A

# HRM - ANTIHISTAMINES

## Products Affected

- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPS
- Promethazine Hcl TABS 12.5MG
- Promethazine Hydrochloride TABS 25MG, 50MG

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Nausea: Diagnosis of Nausea and trial and failure, contraindication, or intolerance to ondansetron or prochlorperazine. Hives/Itching: Trial and failure, contraindication, or intolerance to a non-sedating antihistamine (e.g. desloratadine or levocetirizine). Anxiety: Trial and failure, contraindication, or intolerance to at least two of the following: escitalopram, sertraline, duloxetine, or buspirone.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Anxiety: 12 months: All others: 3 months
<b>Other Criteria</b>	Provider must submit attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older. The drug is being prescribed for a medically accepted indication AND the Prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) and will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the patient.



# ICATIBANT

## Products Affected

- Icatibant Acetate

- Sajazir

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis with labs on two separate dates based on evidence of a normal C1 level in the range of 14 to 40mg/dl and a low C4 level of less than or equal to 14mg/dl as defined by the laboratory performing the test plus a low C1 Inhibitor (C1INH) Antigenic level less than or equal to 19mg/dl normal range 19-37mg/dl, or C1INH Antigenic level below the lower limit of normal as defined by the laboratory performing the test, or a normal C1INH Antigenic level greater than or equal to 19mg/dl and a low C1INH functional level less than or equal to 50%, or below the lower limit of normal as defined by the laboratory performing the test and member must be experiencing at least one symptom of the moderate or severe attack, for example airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Allergist, Immunologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Documentation of diagnosis of Hereditary Angioedema

# INCRELEX

## Products Affected

- Increlex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Patients with closed epiphyses, patients with active or suspected neoplasia
<b>Required Medical Information</b>	Height Measurements and Serum IGF-1 levels three or more STD deviations below normal (based on lab reference range for age and sex), and normal or elevated Growth Hormone levels
<b>Age Restrictions</b>	2 years or older
<b>Prescriber Restrictions</b>	Endocrinologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Discontinuation occurs when linear growth ceases

# INGREZZA

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## Products Affected

- Ingrezza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# ISTURISA

## Products Affected

- Isturisa TABS 1MG, 5MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

# IVERMECTIN

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## Products Affected

- Ivermectin TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite <i>Strongyloides stercoralis</i> OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite <i>Onchocerca volvulus</i> OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months.
<b>Other Criteria</b>	N/A

# JAKAFI

## Products Affected

- Jakafi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Intermediate or High-Risk Myelofibrosis (Myelofibrosis diagnosis includes Primary, Postpolycythemia, and Postessential Thrombocythemia Myelofibrosis). Diagnosis of Polycythemia Vera with trial and failure, contraindication, or intolerance to hydroxyurea. Diagnosis of Steroid-Refractory Acute Graft-Versus-Host Disease. Diagnosis of chronic graft versus host disease (cGVHD). Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# JUXTAPID

## Products Affected

- Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Concomitant use with mod or strong CYP3A4 inhibitors, hepatic impairment, mod or sev (Child-Pugh cat B or C), liver disease, active, including unexplained persistent elevations of serum transaminases, pregnancy
<b>Required Medical Information</b>	Diagnosis of Homozygous Familial Hypercholesterolemia, liver function tests, and negative pregnancy test in women with reproductive potential
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist, Cardiologist
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 6 months
<b>Other Criteria</b>	N/A

# JYNARQUE

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## Products Affected

- Jynarque

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Hypovolemia, hypernatremia: use in patients unable to sense or appropriately respond to thirst, clinically relevant hepatic impairment, anuria, pregnancy, or breastfeeding.
<b>Required Medical Information</b>	Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A



# KALYDECO

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## Products Affected

- Kalydeco

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of CF in patients who have one mutation in the CFTR gene that is responsive to Ivacaftor Potentiation
<b>Age Restrictions</b>	Patient is 1 month of age or older
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# KERENDIA

## Products Affected

- Kerendia

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) defined by one of the following: 1) All of the following: a) urinary albumin-to-creatinine ratio (UACR) of 30 to 300 mg/g, b) estimated glomerular filtration rate (eGFR) greater than or equal to 25 to 60 mL/min/1.73 m <sup>2</sup> , and c) diabetic retinopathy, OR 2) Both of the following: a) UACR of greater than or equal to 300 mg/g and b) eGFR of greater than or equal to 25 mL/min/1.73 m <sup>2</sup> . One of the following: 1) Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following: a) generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy. One of the following: 1) Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB, OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs.

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# KINERET

## Products Affected

- Kineret

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Hypersensitivity to proteins derived from E. coli
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA): Diagnosis of moderately to severely active RA. One of the following: A) Documented trial/failure, contraindication, or intolerance to two of the following products: Enbrel (etanercept), adalimumab, Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), OR B) For continuation of prior therapy if within the past 120 days.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Rheumatologist, Dermatologist, Neurologist, Pediatrician
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: (All) Documentation of positive clinical response to therapy as evidenced by improvement from baseline.

# KORLYM

## Products Affected

- Mifepristone TABS 300MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Type 2 Diabetes Mellitus unrelated to endogenous Cushings, Pregnancy, Use of simvastatin or lovastatin and CYP3A substrates with narrow therapeutic range, Concurrent long-term corticosteroid use, Women w hx of unexplained vaginal bleeding, Women w endometrial hyperplasia w atypia or endometrial carcinoma
<b>Required Medical Information</b>	Covered for indication of Controlling Hyperglycemia secondary to Hypercortisolism in adult patients with endogenous Cushings Syndrome who have Type 2 Diabetes Mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A

# KUVAN

## Products Affected

- Sapropterin Dihydrochloride

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 2 months. Reauth: 3 months
<b>Other Criteria</b>	Prior authorization is to monitor if patient is a responder or nonresponder after therapy has been initiated for 2 months. If phenylalanine levels have decreased after the 2 months, then authorization will continue.

# LEUPROLIDE

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## Products Affected

- Eligard
- Leuprolide Acetate INJ 1MG/0.2ML, 22.5MG
- Lupron Depot (1-month)
- Lupron Depot (3-month)
- Lupron Depot (4-month)
- Lupron Depot (6-month)
- Lupron Depot-ped (1-month) INJ 7.5MG
- Lupron Depot-ped (3-month) INJ 11.25MG
- Lupron Depot-ped (6-month)

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Subject to BvD decision. Leuprolide acetate injection is indicated in the tx of advanced or metastatic prostate cancer, tx of children with Central Precocious Puberty, endometriosis and uterine leiomyomata (fibroids).

# LIDOCAINE

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## Products Affected

- Lidocaine PTCH 5%

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of Post-herpetic Neuropathy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# LUPKYNIS

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## Products Affected

- Lupkynis

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Lupus Nephritis (initial): Diagnosis of active lupus nephritis. Used in combination with immunosuppressive therapy (e.g., mycophenolate mofetil, methylprednisolone).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Lupus Nephritis (initial): Prescribed by or in consultation with a nephrologist or rheumatologist
<b>Coverage Duration</b>	Lupus Nephritis (initial, reauth): 12 months
<b>Other Criteria</b>	Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.



# MAVENCLAD

## Products Affected

- Mavenclad

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Current malignancy, current pregnancy, breastfeeding, or men or women of reproductive potential who do not plan to use effective contraception during therapy and for 6 months after the last dose in each treatment course, HIV infection, active chronic infections (e.g., hepatitis or tuberculosis)
<b>Required Medical Information</b>	Diagnosis of Active SPMS confirmed by progress notes which show a previous RRMS course with increasing disability over the last 6 months or longer. Diagnosis of RRMS and trial and failure, contraindication, or intolerance to two previous disease modifying drugs indicated for the treatment of RRMS
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months, max 24 months
<b>Other Criteria</b>	Documentation that lymphocyte and CBC is being monitored before, during and after treatment. QL up to 10 tablets per 5 day cycle. Max one course per year, consisting of two 4-5 day treatment cycles separated by 23 to 27 days (from last day of first cycle to first day of second cycle). Second course at least 43 weeks after the last dose of the previous year's course. FDA states that treatment beyond 2 years may further increase the risk of malignancy.

# MAVYRET

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## Products Affected

- Mavyret

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Mavyret will not be covered for patients that are requesting Mavyret in combination with another HCV direct-acting antiviral agent
<b>Required Medical Information</b>	Documented diagnosis of Chronic Hepatitis C Virus. Criteria will be applied consistent with current AASLD-IDSA guidance
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hepatologist, Gastroenterologist, Infectious Disease Specialist, HIV Specialist
<b>Coverage Duration</b>	Approval period will be consistent with current AASLD/IDSA guidelines
<b>Other Criteria</b>	N/A

# MEGACE

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## Products Affected

- Megestrol Acetate SUSP 40MG/ML, 625MG/5ML
- Megestrol Acetate TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Evaluate use as a Part D covered diagnosis

# MULPLETA

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## Products Affected

- Mulpleta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Thrombocytopenia with Chronic Liver Disease. Baseline platelet count less than 50,000 platelets/MCL
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	7 days
<b>Other Criteria</b>	Patient scheduled to undergo a medical or dental procedure expected to cause major bleeding within the next 30 days

# NUCALA

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## Products Affected

- Nucala

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# NUEDEXTA

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## Products Affected

- Nuedexta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Pseudobulbar Affect
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Neurologist, Psychiatrist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of clinical benefit from ongoing therapy as demonstrated by a decrease in inappropriate laughing or crying episodes.

# NUPLAZID

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## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Parkinson's Disease- Psychotic Disorder
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# NURTEC

## Products Affected

- Nurtec

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Nurtec will not be approved if it is being used in combination with another calcitonin gene-related peptide (CGRP) inhibitor (injectable or oral). Nurtec will not be approved if being used in combination with Reyvow (lasmiditan).
Required Medical Information	Initial: Diagnosis of moderate/severe migraine with or without aura per International Classification of Headache Disorders. For patients with 4+ migraine days per month, must be one of the following: Doc trial of at least one generic triptan therapy with little to no relief of moderate/severe migraine sx, or doc contraindication to triptan therapy defined as one of the following: 1) History of stroke/transient ischemic attack 2) History of hemiplegic or basilar migraine 3) Peripheral vascular disease, ischemic bowel disease 4) Uncontrolled hypertension 5) Recent use (within 2 weeks) of MAOI 6) Recent use (within 24 hours) of treatment with another 5-HT1 Agonist, ergot-containing or ergotype medication (e.g. methysergide, dihydroergotamine) 7) Ischemic coronary artery disease (angina pectoris, history of myocardial infarction [MI], or doc silent ischemia) 8) Coronary artery vasospasm, including Prinzmetal variant angina, or other significant underlying cardiovascular disease 9) Wolff-Parkinson-White Syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders 10) Patients with risk factors for CAD (e.g. hypertension, hypercholesterolemia, smoker, obesity, diabetes, strong family history of CAD, menopause, male 40 years of age) in whom adequate cardiac evaluation has not ruled out CAD. Preventive Treatment of Episodic Migraine (EM) (initial): Both of the following: diagnosis of EM and patient has 4 to 18 migraine days per month (no more than 18 headache days/month). Two of the following: a) TF/C/I (after 1 month trial) to amitriptyline or venlafaxine, b) TF/C/I (after 1 month trial) to divalproex sodium or topiramate, c) TF/C/I (after 1 month trial) to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol. Medication will not be used in combination with injectable CGRP inhibitor.
Age Restrictions	18 years or older

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<b>Prescriber Restrictions</b>	Neurologist, Pain Specialist, Headache Specialist or Physician who specializes in the treatment of Chronic Migraine Management
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy (reduction in pain, photophobia, phonophobia).

# NUVIGIL

## Products Affected

- Armodafinil

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Treatment of Multiple Sclerosis
<b>Required Medical Information</b>	Diagnosis of Narcolepsy confirmed by Sleep Lab evaluation. Diagnosis of Obstructive Sleep Apnea or Hypopnea Syndrome confirmed by Polysomnography and has score of 10 or more in the Epworth Sleepiness Scale. Diagnosis of Shift-Work Sleep Disorder (SWSD) confirmed by symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, or sleep study demonstrating loss of a normal sleep-wake pattern (e.g. Disturbed Chronobiologic Rhythmicity). No other medical condition or medication accounts for they symptoms.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth): Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD. Narcolepsy (Reauth): Documentation of positive clinical response to prior therapy.

# Ocaliva

## Products Affected

- Ocaliva

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. Diagnosis of primary biliary cholangitis (also known as primary biliary cirrhosis), AND 2. One of the following: 2.1 Both of the following: a. Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after treatment with ursodeoxycholic acid (UDCA) (e.g., ursodiol), and b. Used in combination with ursodeoxycholic acid (UDCA), OR 2.2 History of contraindication or intolerance to ursodeoxycholic acid (UDCA)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hepatologist, Gastroenterologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Patient does not have evidence of advanced cirrhosis (i.e. cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy) , AND Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)

# OCTREOTIDE

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## Products Affected

- Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML, 50MCG/ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# OFEV

## Products Affected

- Ofev

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented baseline liver function tests. Diagnosis of Idiopathic Pulmonary Fibrosis as defined by the American Thoracic Society, or diagnosis of Systemic Sclerosis Associated Interstitial Lung Disease. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype: 1) Diagnosis of Chronic Fibrosing Interstitial Lung Disease, and 2) Patient has a High-Resolution Computed Tomography (HRCT) showing at least 10% of lung volume with fibrotic features, and 3) Disease has a Progressive Phenotype as observed by one of the following: Decline of Forced Vital Capacity (FVC), worsening of respiratory symptoms. or increased extent of fibrosis seen on imaging.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# ONCOLOGY AGENTS

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## Products Affected

- Abiraterone Acetate
- Akeega
- Alecensa
- Alunbrig
- Augtyro
- Ayvakit
- Balversa
- Bexarotene CAPS
- Bosulif
- Braftovi CAPS 75MG
- Brukinsa
- Cabometyx
- Calquence
- Caprelsa
- Cometriq
- Copiktra
- Cotellic
- Daurismo
- Erivedge
- Erleada
- Erlotinib Hydrochloride TABS
- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO
- Fotivda
- Fruzaqla
- Gavreto
- Gefitinib
- Gilotrif
- Ibrance
- Iclusig
- Idhifa
- Imatinib Mesylate
- Imbruvica CAPS
- Imbruvica SUSP
- Imbruvica TABS 420MG
- Inlyta
- Inqovi
- Inrebic
- Iwilfin
- Jaypirca
- Kisqali
- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose
- Koselugo
- Krazati
- Lapatinib Ditosylate
- Lenalidomide
- 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
- Lonsurf
- Lorbreana
- Lumakras
- Lynparza TABS
- Lytgobi
- Matulane
- Mekinist
- Mektovi
- Nerlynx
- Ninlaro
- Nubeqa
- Odomzo
- Ogsiveo
- Ojemda
- Ojjaara
- Orgovyx
- Orserdu
- Pazopanib Hydrochloride
- Pemazyre
- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose

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- Pomalyst
- Qinlock
- Retevmo
- Rezlidhia
- Rozlytrek
- Rubraca
- Rydapt
- Scemblix
- Sorafenib Tosylate TABS
- Sprycel
- Stivarga
- Sunitinib Malate
- Tabrecta
- Tafenlar
- Tagrisso
- Talzenna
- Tassigna
- Tazverik
- Tepmetko
- Tibsovo
- Toremifene Citrate
- Torpenz
- Trelstar Mixject
- Tretinoin CAPS
- Truqap TABS
- Tukysa
- Turalio CAPS 125MG
- Vanflyta
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Vitrakvi
- Vizimpro
- Vonjo
- Welireg
- Xalkori
- Xospata
- Xpovio
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly
- Xtandi
- Yonsa
- Zejula TABS
- Zelboraf
- Zolinza
- Zydelig
- Zykadia TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For requests of brand agents within this policy that have a generic available, must have trial/failure of generic agent first
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Ayvakit: Prescribed by or in consultation with an oncologist/hematologist, allergist, or immunologist. All others: Oncologist, Hematologist, Rheumatologist, Transplant Specialist, Neurologist

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<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	<p>Tx of cancer type listed in an accepted compendia AHFS-DI, NCCN, Thomson Micromedex, Clinical Pharmacology, and Lexi-Drugs as outlined in the Medicare Benefit Policy Manual Ch. 15 Section 50.4.5(c). Everolimus will also be approved for a documented diagnosis of Tuberous Sclerosis Complex Associated Partial Onset Seizures. Imbruvica will also be approved for a documented diagnosis of Graft vs Host Disease. Ayvakit will also be approved for advanced systemic mastocytosis or indolent systemic mastocytosis. Imatinib mesylate and Rydapt will also be approved for a documented diagnosis of aggressive systemic mastocytosis (ASM).</p>



# OPSUMIT

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## Products Affected

- Opsumit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Patients with severe anemia, Patients on strong CYP3A4 inducers (rifampin) or CYP3A4 inhibitors (ketoconazole, ritonavir), Pregnant patients
<b>Required Medical Information</b>	Documentation of results of acute vasoreactivity testing
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist, Cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# ORAL FENTANYL PRODUCTS

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## Products Affected

- Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented tolerance to current long acting opioid regimen and requires immediate-release breakthrough opioid. Opioid tolerance defined as pt taking at least 60mg morphine/day, 25mcg transdermal fentanyl/hr, or an equianalgesic dose of another opioid for a week or longer.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A

# ORENCIA

## Products Affected

- Orenzia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML

- Orenzia Clickject

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Polyarticular Juvenile Idiopathic Arthritis (PJIA): Diagnosis of moderately to severely active PJIA. One of the following: A) Trial and failure, contraindication, or intolerance to two of the following: Enbrel (etanercept), adalimumab, Xeljanz/Xeljanz XR (tofacitinib), OR B) For continuation of prior therapy if within the past 120 days. Psoriatic Arthritis (PSA): Diagnosis of active PSA with One of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail involvement. Rheumatoid Arthritis (RA): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month Trial/failure, intolerance, or contraindication to one disease modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Rheumatologist or Dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: (All) Documentation of positive clinical response to therapy as evidenced by improvement from baseline.

# ORFADIN

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## Products Affected

- Nitisinone

- Orfadin SUSP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# ORKAMBI

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## Products Affected

- Orkambi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of CF and patients who are homozygous for the F508del mutation in the CFTR gene
<b>Age Restrictions</b>	1 year or older
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# ORLADEYO

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## Products Affected

- Orladeyo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis has been confirmed by C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: C1-INH antigenic level below the lower limit of normal OR C1-INH functional level below the lower limit of normal, documentation that medication will be used for prophylaxis against Hereditary angioedema (HAE) attacks
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an immunologist or an allergist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# OSPHERA

## Products Affected

- OspheNa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Dyspareunia: Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Trial and failure, contraindication, or intolerance to one of the following: Estrace (estradiol) vaginal cream or Premarin (conjugated estrogens) vaginal cream. Vaginal Dryness: Diagnosis of vaginal dryness with trial and failure, contraindication, or intolerance to one of the following: Estrace (estradiol) vaginal cream or Premarin (conjugated estrogens) vaginal cream.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Dyspareunia and vaginal dryness (Reauth): Documentation of positive clinical response to therapy

# OTEZLA

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## Products Affected

- Otezla

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review



# OXERVATE

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## Products Affected

- Oxervate

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Doc of Stage 2 or 3 neurotrophic keratitis, with decreased or absent corneal sensation, must include which eye(s) is/are affected, Doc that any ocular surface disease is currently being treated with conventional therapies (e.g. antibiotic ointments)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Ophthalmologist
<b>Coverage Duration</b>	8 weeks
<b>Other Criteria</b>	Reauth: Documentation of recurrence of neurotrophic keratitis

## PART D VS. EXCLUDED

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### Products Affected

- Invexxy Maintenance Pack
- Invexxy Starter Pack
- Lidocaine OINT 5%
- Lidocaine Hydrochloride EXTERNAL SOLN
- Lidocaine/prilocaine CREA

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

# PENNSAID

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## Products Affected

- Diclofenac Sodium EXTERNAL SOLN 1.5%

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# PH PDE5 INHIBITORS

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## Products Affected

- Alyq
- Sildenafil Citrate TABS 20MG
- Tadalafil TABS 20MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Patients receiving nitrates in any form, either regularly or intermittently.
<b>Required Medical Information</b>	Documented previous failure of or contraindication to a generic formulary CCB if testing reveals vasoactivity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist, Cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# PRETOMANID

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## Products Affected

- Pretomanid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Confirmed susceptibility data that indicate member has pulmonary Multi-Drug Resistant Tuberculosis (MDR-TB)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Infectious Disease Specialist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Documentation that Pretomanid will be used in combination with Sirturo (bedaquiline) and linezolid.

# PROCYSBI

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## Products Affected

- Procysbi PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# PROMACTA AND NPLATE

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## Products Affected

- Promacta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# PROVIGIL

## Products Affected

- Modafinil TABS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Treatment of Multiple Sclerosis
<b>Required Medical Information</b>	Diagnosis of Narcolepsy confirmed by Sleep Lab evaluation. Diagnosis of Obstructive Sleep Apnea or Hypopnea Syndrome confirmed by Polysomnography and has score of 10 or more in the Epworth Sleepiness Scale. Diagnosis of Shift-Work Sleep Disorder (SWSD) confirmed by symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, or sleep study demonstrating loss of a normal sleep-wake pattern (e.g. Disturbed Chronobiologic Rhythmicity). No other medical condition or medication accounts for they symptoms.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth): Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD. Narcolepsy (Reauth): Documentation of positive clinical response to prior therapy.



# PULMOZYME

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## Products Affected

- Pulmozyme SOLN 2.5MG/2.5ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Subject to BvD decision. Diagnosis of Cystic Fibrosis.

# QUALAQUIN

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## Products Affected

- Quinine Sulfate CAPS 324MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Prior authorization to ensure use for malaria

# RAVICTI

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## Products Affected

- Ravicti

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Hypersensitivity to phenylbutyrate
<b>Required Medical Information</b>	Diagnosis or Chronic Disorder of the Urea Cycle, metabolism confirmed by enzymatic, biochemical, or genetic testing
<b>Age Restrictions</b>	2 months or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Doc trial and failure, intolerance, or contraindication to Buphenyl

# REGRANEX

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## Products Affected

- Regranex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of diabetic lower extremity ulcer
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A

# RELISTOR

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## Products Affected

- Relistor INJ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# REYVOW

## Products Affected

- Reyvow

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Reyvow will not be approved if being used in combination with Nurtec (rimegepant) or Ubrelvy (ubrogepant)
<b>Required Medical Information</b>	Initial: Diagnosis of moderate to severe migraine with or without aura according to the International Classification of Headache Disorders. For patients with 4 or more migraine days per month, there must be one of the following: Documented trial of at least one generic triptan therapy with little to no relief of moderate/severe migraine symptoms, or documented contraindication to triptan therapy defined as one of the following: I. History of stroke or transient ischemic attack II. History of hemiplegic or basilar migraine III. Peripheral vascular disease, ischemic bowel disease IV. Uncontrolled hypertension V. Recent use (within 2 weeks) of MAO Inhibitors VI. Recent use (within 24 hours) of treatment with another 5-HT1 Agonist, or an ergot-containing or ergotype medication (e.g. methysergide, dihydroergotamine) VII. Ischemic coronary artery disease (angina pectoris, history of myocardial infarction [MI], or documented silent ischemia) VIII. Coronary artery vasospasm, including Prinzmetal variant angina, or other significant underlying cardiovascular disease IX. Wolff- Parkinson-White Syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders X. Patients with risk factors for CAD (e.g. hypertension, hypercholesterolemia, smoker, obesity, diabetes, strong family history of CAD, menopause, male 40 years of age) in whom adequate cardiac evaluation has not ruled out CAD
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Neurologist, Pain Specialist, Headache Specialist or Physician who specializes in the treatment of Chronic Migraine Management
<b>Coverage Duration</b>	Initial: 12 months. Reauth: 12 months (with documentation of beneficial response).
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy (reduction in pain, photophobia, phonophobia)

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Last Updated: 10/10/2024

# REZUROCK

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## Products Affected

- Rezurock

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients.
<b>Coverage Duration</b>	cGVHD (initial, reauth): 12 months
<b>Other Criteria</b>	cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.

# RINVOQ

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## Products Affected

- Rinvoq

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review



# RUCONEST

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## Products Affected

- Ruconest

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Patients with laryngeal attack
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	13 years or older
<b>Prescriber Restrictions</b>	Allergist, Immunologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# SAMSCA

## Products Affected

- Tolvaptan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	To raise Serum Na urgently to prevent or to treat serious neurological symptoms
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Tolvaptan is indicated for the tx of clinically significant hypervolemic and euvoletic hyponatremia (serum sodium 125 meq/L or less marked hyponatremia that is symptomatic), including patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH). 1-3. pt req intervention to raise serum Na urgently to prevent or to treat serious neurological symptoms should not be treated with tolvaptan. 1 it has not been established that raising serum sodium with tolvaptan provides a symptomatic benefit to patients. Should be initiated and reinitiated in patients only in a hospital where serum sodium can be monitored closely

# SAVELLA

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## Products Affected

- Savella

- Savella Titration Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. All FDA-approved Indications, AND 2. Diagnosis of Fibromyalgia, AND 3. T/F/C/I to a. duloxetine, and b. gabapentin or pregabalin
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# SIGNIFOR

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## Products Affected

- Signifor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Cushing's Syndrome/Disease, baseline fasting plasma glucose and/or HbA1c. Documentation that the patient had surgery that was not curative or is not a candidate for surgery.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Endocrinologist
<b>Coverage Duration</b>	Initials: 3 months. Reauth: 12 months.
<b>Other Criteria</b>	N/A

# SIRTURO

## Products Affected

- Sirturo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Diagnosis of latent infection due to mycobacterium, extrapulmonary or drug sensitive TB or Non-TB mycobacterial infection
<b>Required Medical Information</b>	Multi-Drug resistant TB with confirmed susceptibility data that indicate member has pulmonary MDR-TB
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Infectious Disease Specialist
<b>Coverage Duration</b>	24 weeks
<b>Other Criteria</b>	Must be used in combination with at least three other drugs to which the members MDR-TB isolate has been shown to be susceptible in vitro. MDR-TB refers to an isolate of M. TB that is resistant to at least isoniazid and rifampin and possibly additional agents. Treatment failure refers to failure of cultures to become negative during course of tx or reappearance of positive cultures after cultures convert to negative during treatment

# SKYRIZI

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML

- Skyrizi Pen

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Crohn's (CD): Diagnosis of moderately to severely active CD with One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications such as obstruction, fever, abdominal mass, abnormal lab values (e.g., CRP), CD Activity Index (CDAI greater than 220). TF/C/I to one of the following conventional therapies: corticosteroid, immunosupp (e.g. azathioprine, 6-MP, methotrexate).Psoriasis (PSO): Diagnosis of moderate to severe chronic plaque psoriasis with One of the following: Greater than or equal to 3% body surface area involvement, Severe scalp psoriasis, Palmoplantar (i.e., palms, soles), facial, or genital involvement AND Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar. Psoriatic Arthritis (PsA): Diagnosis of active psoriatic arthritis (PsA) with One of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail involvement.</p>
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Dermatologist, Rheumatologist, or Gastroenterologist
<b>Coverage Duration</b>	12 months

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<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to therapy: Reduction in the body surface area (BSA) involvement from baseline or improvement in symptoms (e.g., pruritus, inflammation) from baseline, or Reduction in the total active (swollen and tender) joint count from baseline, or at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
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# SOVALDI

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## Products Affected

- Sovaldi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review



# STELARA

## Products Affected

- Stelara INJ 45MG/0.5ML, 90MG/ML

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Crohn's Disease (CD): Diagnosis of moderately to severely active CD with One of the following: Frequent diarrhea and abdominal pain, At least 10% weight loss, Complications such as obstruction, fever, abdominal mass, Abnormal lab values (e.g., CRP), CD Activity Index (CDAI greater than 220) . Trial/failure, contraindication, or intolerance to one of the following: corticosteroid or immunosuppressant (azathioprine, 6-MP, or methotrexate) therapy. Psoriasis (PSO): Diagnosis of severe plaque psoriasis with One of the following: Greater than or equal to 3% body surface area involvement, Severe scalp psoriasis, Palmoplantar (i.e., palms, soles), facial, or genital involvement, AND Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar. Psoriatic Arthritis (PSA): Diagnosis of active PSA with One of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail involvement, AND Patient's weight is greater than 100 kg (220 lbs) for 90mg/mL strength. Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC with One of the following: Greater than 6 stools per day, Frequent blood in the stools, Frequent urgency, Presence of ulcers, Abnormal lab values (e.g., hemoglobin, ESR, CRP), Dependent on, or refractory to, corticosteroids, AND Trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], Azathioprine (Imuran), Corticosteroids (e.g., prednisone, methylprednisolone)</p>
<b>Age Restrictions</b>	Psoriatic Arthritis: 6 years or older. Plaque Psoriasis: 6 years or older.

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<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Rheumatologist, Gastroenterologist, Dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reatuth (ALL): Documentation of positive clinical response to therapy as evidenced by improvement from baseline

# SUCRAID

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## Products Affected

- Sucraid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Sucrase-isomaltase deficiency, congenital
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# SUNOSI

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## Products Affected

- Sunosi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Excessive Daytime Sleepiness associated with Narcolepsy confirmed by sleep lab evaluation or Diagnosis of Excessive Daytime Sleepiness associated with Obstructive Sleep Apnea (OSA) confirmed by sleep study. Documented trial and failure, intolerance, or contraindication to armodafinil or modafinil
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# SYMDEKO

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## Products Affected

- Symdeko

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of cystic fibrosis and homozygous for the F508del mutation or at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor
<b>Age Restrictions</b>	6 years or older
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# SYMLIN

## Products Affected

- Symlinpen 120

- Symlinpen 60

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Confirmed dx of gastroparesis. Need for meds to stimulate GI motility. HBA1c greater than 9%. Recurrent severe hypoglycemia requiring assistance in the last 6 mo. Presence of hypoglycemia unawareness. Ped patients.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Failure to achieve adequate glycemic control for adults who take mealtime insulin

# TADALAFIL ONCE DAILY

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## Products Affected

- Tadalafil TABS 2.5MG, 5MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# TAFAMIDIS

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## Products Affected

- Vyndamax

- Vyndaqel

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	1. All FDA-approved Indications, AND 2. Diagnosis of amyloid cardiomyopathy (ATTR-CM) with TTR mutation or amyloid deposits, AND 3. One of the following: a. History of heart failure, with at least one prior hospitalization for heart failure, OR b. Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema), AND Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A



# TAKHZYRO

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## Products Affected

- Takhzyro

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prophylaxis of Hereditary Angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Immunologist, Allergist, Rheumatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# TALTZ

## Products Affected

- Taltz

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Ankylosing Spondylitis (AS)(Initial): Diagnosis of active AS. One of the following: A) Trial/failure, contraindication, or intolerance to two of the following: 1) Cosentyx (secukinumab), 2) adalimumab, 3) Enbrel (etanercept), 4) Xeljanz/Xeljanz XR (tofacitinib), OR B) For continuation of prior therapy if within the past 120 days. Non-Radiographic Axial Spondyloarthritis (NR-AXSPA)(Initial): Diagnosis of NR-AXSPA. Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.), AND documented TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) at maximally indicated doses, AND one of the following: A) TF/C/I to Cosentyx, OR B) For continuation of prior therapy if within the past 120 days. Psoriasis (PSO)(Initial): Diagnosis of chronic moderate to severe plaque psoriasis with One of the following: Greater than or equal to 3% body surface area involvement, Severe scalp psoriasis, Palmoplantar (i.e., palms, soles), facial, or genital involvement . One of the following: A) Trial/failure, contraindication, or intolerance to two of the following: 1) Cosentyx (secukinumab), 2) Enbrel (etanercept), 3) adalimumab, 4) Otezla, 5) Skyrizi (risankizumab), 6) Stelara (ustekinumab) OR B) For continuation of prior therapy if within the past 120 days.
<b>Age Restrictions</b>	PSO: 6 years or older, All others: 18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Rheumatologist or Dermatologist
<b>Coverage Duration</b>	12 months

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<b>Other Criteria</b>	Psoriatic Arthritis (PSA): Diagnosis of active psoriatic arthritis (PsA) with One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, AND One of the following: A) Trial/failure, contraindication, or intolerance to TWO of the following: 1) Cosentyx (secukinumab), 2) Enbrel (etanercept) , 3) adalimumab, 4) Orencia, 5) Otezla, 6) Rinvoq (upadacitinib, 7) Skyrizi (risankizumab), 8) Stelara (ustekinumab), 9) Xeljanz/Xeljanz XR (tofacitinib) OR B) For continuation of prior therapy if within the past 120 days. (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline.
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# TARGRETIN

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## Products Affected

- Bexarotene GEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g. corticosteroids {e.g. clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [e.g. interferons]).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist, Dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy

# TAVNEOS

## Products Affected

- Tavneos

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: a) Granulomatosis with polyangiitis (GPA) OR b) Microscopic polyangiitis (MPA). Diagnosis is confirmed by one of the following: a) ANCA test positive for proteinase 3 (PR3) antigen, b) ANCA test positive for myeloperoxidase (MPO) antigen, OR c) Tissue biopsy. Patient is receiving concurrent immunosuppressant therapy with one of the following: a) cyclophosphamide OR b) rituximab. One of the following: a) Patient is concurrently on glucocorticoids (e.g., prednisone) OR b) History of contraindication or intolerance to glucocorticoids (e.g., prednisone).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial, Reauth: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist
<b>Coverage Duration</b>	Initial, Reauth: 12 months
<b>Other Criteria</b>	Reauth: Patient does not show evidence of progressive disease while on therapy. Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab).

# TAZORAC

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## Products Affected

- Tazarotene CREA 0.1%
- Tazarotene GEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# TCAS

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## Products Affected

- Clomipramine Hydrochloride
- Doxepin Hcl CAPS 75MG
- Doxepin Hcl CONC
- Doxepin Hydrochloride CAPS 100MG, 10MG, 150MG, 25MG, 50MG
- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Imipramine Pamoate CAPS 150MG, 75MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# TERIPARATIDE

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## Products Affected

- Teriparatide INJ 620MCG/2.48ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review



# TESTOSTERONE REPLACEMENT

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## Products Affected

- Testosterone GEL 10MG/ACT, 20.25MG/1.25GM, 25MG/2.5GM, 40.5MG/2.5GM, 50MG/5GM
- Testosterone Pump

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# TETRABENAZINE

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## Products Affected

- Tetrabenazine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of chorea associated with Huntington Disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# THALOMID

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## Products Affected

- Thalomid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Erythema nodosum leprosum, Erythema nodosum leprosum prophylaxis, Multiple myeloma newly diagnosed in combination with dexamethasone
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist, Infectious Disease Specialist, or Dermatologist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A

# TOBRAMYCIN

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## Products Affected

- Tobramycin NEBU 300MG/5ML
- Tobi Podhaler

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of Cystic Fibrosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist, Infectious Disease Specialist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# TREPROSTINIL

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## Products Affected

- Orenitram
- Orenitram Titration Kit Month 1
- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3
- Tyvaso Dpi Maintenance Kit
- Tyvaso Dpi Titration Kit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of results of acute vasoreactivity testing
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist, Cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	The drug is prescribed by a physician experienced in the management of pulmonary vascular disease for the treatment of pulmonary arterial hypertension in patients with NYHA Class II, III or IV symptoms.

# TRETINOIN/AZELAIC ACID

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## Products Affected

- Azelex
- Tretinoin CREA
- Tretinoin GEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Cosmetic purposes (e.g., wrinkles, photoaging)
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# TRIKAFTA

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## Products Affected

- Trikafta TBPK 100MG; 0; 50MG
- Trikafta THPK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of Cystic fibrosis and documentation that member has at least one F508del mutation in the CFTR gene
<b>Age Restrictions</b>	For granule packets: patient is at least 2 to less than 6 years of age. For tablets: patient is 6 years of age or older.
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# TYENNE

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## Products Affected

- Tyenne INJ 162MG/0.9ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review



# UPTRAVI

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## Products Affected

- Uptravi TABS
- Uptravi Titration Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of pulmonary arterial hypertension. Documented trial and failure, contraindication, or intolerance to sildenafil
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Pulmonologist, Cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# VALCHLOR

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## Products Affected

- Valchlor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# VEOZAH

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## Products Affected

- Veozah

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: Diagnosis of moderate to severe vasomotor symptoms due to menopause.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial, Reauth: 6 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy.

# VERQUVO

## Products Affected

- Verquvo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Heart Failure (CHF) (initial): Diagnosis of CHF. Patient has an ejection fraction less than 45 percent. Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms. One of the following: A) Patient was hospitalized for heart failure within the last 6 months, or B) Patient used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), 2) Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan), or 3) Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)], B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., spironolactone].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy as evidenced by improvement from baseline

Formulary ID: 25411, Version: 10, Effective Date: 01/01/2025

Last Updated: 10/10/2024

# VIBERZI

## Products Affected

- Viberzi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Irritable Bowel Syndrome with Diarrhea (IBS-D): Diagnosis of IBS-D, Documented failure to respond or contraindication to loperamide, or Documented failure to respond or contraindication to at least one bile acid sequestrant (e.g. cholestyramine, colestipol, colesevelam), or Documented failure to respond or contraindication to at least one antispasmodic agent (e.g. dicyclomine, hyoscyamine).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# VIGAFYDE

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## Products Affected

- Vigafyde

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	Pending CMS Review
<b>Off-Label Uses</b>	Pending CMS Review
<b>Exclusion Criteria</b>	Pending CMS Review
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	Pending CMS Review
<b>Prescriber Restrictions</b>	Pending CMS Review
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review

# VORICONAZOLE INJECTION

## Products Affected

- Voriconazole INJ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA). Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by <i>Scedosporium apiospermum</i> (asexual form of <i>Pseudallescheria boydii</i> ) or <i>Fusarium</i> spp. including <i>Fusarium solani</i> . For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 weeks
<b>Other Criteria</b>	N/A

# VOWST

## Products Affected

- Vowst

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following: 1) Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for two consecutive days, and 2) A positive stool test for C.difficile toxin or toxigenic C.difficile. Patient has a history of two or more recurrent episodes of CDI within 12 months. All of the following: 1) Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst: oral vancomycin or Difucid (fidaxomicin), 2) Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst, and 3) Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days).
<b>Age Restrictions</b>	Patient is 18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist or infectious disease specialist.
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	N/A



# XELJANZ

## Products Affected

- Xeljanz

- Xeljanz Xr

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or a potent immunosuppressant (e.g., azathioprine, cyclosporine)
<b>Required Medical Information</b>	Ankylosing Spondylitis (AS): Diagnosis of active ankylosing spondylitis with Minimum duration of a one-month Trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) at maximally indicated doses. AND Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel (etanercept), adalimumab). Polyarticular Juvenile Idiopathic Arthritis (PJIA): Diagnosis of active PJIA with a minimum duration of a 6-week Trial/failure, contraindication, or intolerance to one of the following disease modifying anti-rheumatic drugs (DMARDs): leflunomide, methotrexate, AND Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel (etanercept), adalimumab). Psoriatic Arthritis (PSA): Diagnosis of active PSA with One of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail involvement, AND Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel (etanercept), adalimumab). Rheumatoid Arthritis (RA): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month Trial/failure, intolerance, or contraindication to one disease modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine) AND Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab).
<b>Age Restrictions</b>	JIA: 2 years or older, All others: 18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Rheumatologist or Gastroenterologist

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<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	<p>Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC with One of the following: Greater than 6 stools per day, Frequent blood in the stools, Frequent urgency, Presence of ulcers, Abnormal lab values (e.g., hemoglobin, ESR, CRP), Dependent on, or refractory to, corticosteroids, AND Trial/failure, intolerance, or contraindication to a corticosteroid (e.g., prednisone, methylprednisolone), immunosuppressant, or aminosalicylates (e.g. azathioprine, 6-MP, methotrexate, mesalamine, osalazine, sulfasalazine), AND Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab).</p> <p>Reauth: (All): Documentation of positive clinical response to therapy as evidenced by improvement from baseline Patient is not receiving in combination other JAK inhibitors, biologic DMARDs, or with a potent immunosuppressant (e.g., azathioprine, cyclosporine)</p>

# XERMELO

## Products Affected

- Xermelo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months AND used in combination with SSA therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
<b>Coverage Duration</b>	Initial: 6 months. Reauth: 12 months
<b>Other Criteria</b>	Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy.

# XGEVA

## Products Affected

- Xgeva

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Multiple Myeloma (MM/Bone Metastasis from Solid Tumors (BMST): One of the following: 1) Diagnosis of Multiple Myeloma or 2) Diagnosis of solid tumors (e.g. breast cancer, kidney cancer, prostate cancer, thyroid cancer), and documented evidence of one or more metastatic bone lesions. Giant Cell Tumor of Bone (GCTB): Both of the following: 1) Diagnosis of Giant Cell Tumor of Bone and 2) One of the following: A) Tumor is unresectable, or B) Surgical resection is likely to result in severe morbidity. Hypercalcemia of Malignancy (HCM): Both of the following: 1) Diagnosis of Hypercalcemia of Malignancy, and 2) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (e.g. pamidronate, Zometa (zoledronic acid)).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	MM/BMST, GCTB: 12 months. HCM: 2 months.
<b>Other Criteria</b>	Approve for continuation of prior therapy

# XIFAXAN

## Products Affected

- Xifaxan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	Allergy to Rifamycin agents
<b>Required Medical Information</b>	200mg: Doc dx of travelers' diarrhea caused by noninvasive strains of E. Coli and doc trial and failure, contraindication, or intolerance to a fluoroquinolone or azithromycin. 500mg: Doc dx of Hepatic Encephalopathy and failure to respond to lactulose or neomycin. Or Doc dx of IBS-D without constipation defined as the presence of loose or watery stools with equal to or greater than 25% of bowel movements and hard or lumpy stools with less than 25% of bowel movements and failure to respond to loperamide.
<b>Age Restrictions</b>	Travelers Diarrhea: 12 years or older. Hepatic Encephalopathy and IBS-D without constipation: 18 years or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Travelers Diarrhea: 3 days. Hepatic Encephalopathy: 12 months. IBS-D without Constipation: 14 days.
<b>Other Criteria</b>	For IBS-D without constipation max 3 treatments per calendar year

# XOLAIR

## Products Affected

- Xolair

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Asthma: Dx severe persistent asthma, doc reactivity to at least 1 perennial aeroallergen, pretreatment Ige greater than 30IU/mL, asthma sx inadequately cont w/max tol dose of inhaled corticosteroid and LABA. CIU: Doc itchy hives for at least 6 wks and one of the following unless otherwise contraindicated: Doc fail on at least 2 diff H1 antihistamines at max tol dose or doc fail of one H1 antihist at max tol dose and inadequate response to montelukast or doc fail of one H1 antihist at max tol dose and used in comb w H2 antag at max tol dose
<b>Age Restrictions</b>	Asthma: 6 years or older. CIU: 12 years or older.
<b>Prescriber Restrictions</b>	Allergist, Pulmonologist, Dermatologist, Immunologist, Otolaryngologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Dose does not exceed FDA label max for Asthma or CIU

# XYREM

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## Products Affected

- Sodium Oxybate

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of narcolepsy confirmed by sleep lab evaluation or member has episodes of cataplexy including hypnagogic hallucinations and/or sleep paralysis or member has excessive daytime sleepiness with symptoms that limit the ability to perform normal daily activities
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# ZAVESCA

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## Products Affected

- Miglustat

- Yargesa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Enzyme assay demonstrating deficiency of beta-glucocerebrosidase enzyme activity
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For treatment of adult patients with mild to moderate Type 1 Gaucher Disease for whom ERT is not a therapeutic option (e.g. due to constraints such as allergy, hypersensitivity, or poor venous access)



# ZEPATIER

## Products Affected

- Zepatier

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	All of the following: A) Criteria will be applied consistent with current AASLD/IDSA guideline and B) Patient does not have moderate to severe hepatic impairment (e.g. Child-Pugh Class B or C) and C) For Genotype 1a, patient has been tested for the presence of NS5A resistance-associated polymorphisms (e.g. polymorphisms at amino acid positions 28, 30, 31, or 93)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gastroenterologist, Infectious Disease Specialist, Hepatologist
<b>Coverage Duration</b>	Coverage duration will follow recommendation set forth by the AASLD
<b>Other Criteria</b>	N/A

# ZEPOSIA

## Products Affected

- Zeposia
- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

PA Criteria	Criteria Details
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. Ulcerative Colitis (UC) (init): Diagnosis of moderately to severely active UC. One of the following: a) Trial and failure, contraindication, or intolerance to both of the following, or attestation demonstrating a trial may be inappropriate: adalimumab, Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a Gastroenterologist , or Neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of positive clinical response to therapy as evidenced by improvement from baseline

# ZTALMY

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## Products Affected

- Ztalmy

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Requires: 1. Diagnosis of a cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD), AND Patient has a mutation in the CDKL5 gene, with Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine), OR 2. For continuation of prior therapy.
<b>Age Restrictions</b>	2 years or older
<b>Prescriber Restrictions</b>	Neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# ZURZUVAE

## Products Affected

- Zurzuvae

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Postpartum Depression (PPD): One of the following: A) Diagnosis of severe PPD or B) Both of the following: a) Diagnosis of mild to moderate PPD, and b) Trial and failure, contraindication, or intolerance to at least one oral SSRI or SNRI (e.g., escitalopram, duloxetine). Onset of symptoms in the third trimester or within 4 weeks of delivery. Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae.
<b>Age Restrictions</b>	PPD: Patient is 18 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	Approve for continuation of prior therapy.

## PART B VERSUS PART D

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### Products Affected

- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Amphotericin B INJ
- Arformoterol Tartrate
- Astagraf XL
- Azathioprine TABS
- Bivigam INJ 5GM/50ML
- Budesonide SUSP
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix E 2.75%/dextrose 5% INJ 570MG/100ML; 316MG/100ML; 33MG/100ML; 5GM/100ML; 515MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 110MG/100ML; 454MG/100ML; 154MG/100ML; 261MG/100ML; 187MG/100ML; 138MG/100ML; 217MG/100ML; 112MG/100ML; 116MG/100ML; 50MG/100ML; 11MG/100ML; 160MG/100ML
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinisol Sf 15%
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine Modified
- Dronabinol
- Engerix-b
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Gammagard Liquid INJ 2.5GM/25ML
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 5GM/50ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heplisav-b
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nutrilipid
- Octagam INJ 1GM/20ML, 2GM/20ML
- Ondansetron Hcl SOLN
- Ondansetron Hydrochloride TABS
- Ondansetron Odt TBP 4MG, 8MG
- Pentamidine Isethionate INHALATION SOLR
- Plenamaine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML

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- Prehevbrio
- Premasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 356MG/100ML;  
390MG/100ML; 34MG/100ML;  
152MG/100ML
- Privigen INJ 20GM/200ML
- Prograf PACK
- Prosol
- Rabavert
- Recombivax Hb
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Travasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 500MG/100ML;  
356MG/100ML; 390MG/100ML;  
34MG/100ML; 152MG/100ML
- Trophamine INJ 0.54GM/100ML;  
1.2GM/100ML; 0.32GM/100ML; 0; 0;  
0.5GM/100ML; 0.36GM/100ML;  
0.48GM/100ML; 0.82GM/100ML;  
1.4GM/100ML; 1.2GM/100ML;  
0.34GM/100ML; 0.48GM/100ML;  
0.68GM/100ML; 0.38GM/100ML;  
5MEQ/L; 0.025GM/100ML;  
0.42GM/100ML; 0.2GM/100ML;  
0.24GM/100ML; 0.78GM/100ML

## Details

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

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