

Medications Requiring Prior Authorization

Effective: May 1, 2024

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 is a health plan with a Medicare contract. Enrollment in FirstCarolinaCare 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

Products Affected

- Aralast Np INJ 1000MG, 500MG
- Glassia
- Prolastin-c
- Zemaira

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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%
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Subject to BvD decision. Coverage is limited to a dosage of 60mg/kg weekly.

ABELCET

Products Affected

- Abelcet

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

ACTEMRA

Products Affected

- Actemra
- Actemra Actpen

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	All Indications (initial, reauth): Patient is not receiving Actemra in combination with a biologic DMARD (e.g. Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)).
Required Medical Information	Polyarticular Juvenile Idiopathic Arthritis (PJIA): Diagnosis of active PJIA and one of the following: A) Trial/failure, contraindication, or intolerance to TWO of the following: Enbrel (etanercept), Humira (adalimumab), Orencia, Xeljanz/Xeljanz XR (tofacitinib) OR B) For continuation of prior therapy if within the past 120 days. Rheumatoid Arthritis (RA): Diagnosis of moderately to severely active RA and one of the following: A) Trial and failure, contraindication, or intolerance to TWO of the following: Enbrel (etanercept), Humira (adalimumab), Orencia, Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) OR B) For continuation of prior therapy if within the past 120 days. Systemic Juvenile Idiopathic Arthritis (SJIA): Diagnosis of active SJIA and a trial/failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally indicated doses: a minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen), OR a minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone), OR a minimum duration of a 3-month trial and failure of methotrexate.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist or Pulmonologist
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of positive clinical response to therapy as evidenced by improvement from baseline

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ADEMPAS

Products Affected

- Adempas

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

AIMOVIG

Products Affected

- Aimovig

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concomitant use with another Calcitonin Gene-Related Peptide (CGRP) Inhibitor.
Required Medical Information	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.
Age Restrictions	EM, CM (initial): 18 years or older
Prescriber Restrictions	Neurologist, Headache Specialist, or Pain Specialist.
Coverage Duration	EM, CM (Initial): 6 months. EM, CM (Reauth): 12 months.
Other Criteria	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.

ALDURAZYME

Products Affected

- Aldurazyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme assay demonstrating deficiency of alpha-l-iduronidase enzyme activity or DNA testing
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For patients with Hurler and Hurler-Scheie forms of MPS I and for patients with the Scheie form who have moderate-to-severe symptoms

AMBISOME

Products Affected

- Amphotericin B Liposome

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	Subject to BvD decision.

AMBRISENTAN

Products Affected

- Ambrisentan

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

AMITRIPTYLINE

Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Provider must submit attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older.

ANTIEMETIC THERAPIES

Products Affected

- Aponvie
- Aprepitant CAPS
- Cinvanti
- Emend INJ
- Emend SUSR
- Fosaprepitant Dimeglumine

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Subject to BvD decision.

APOKYN

Products Affected

- Apomorphine Hydrochloride INJ

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

ARANESP

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

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

ARCALYST

Products Affected

- Arcalyst

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Discontinuation with serious infections, concurrent use of TNFS (increased infection risk), Latent TB
Required Medical Information	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).
Age Restrictions	CAPS, FCAS, MWS: 12 years or older.
Prescriber Restrictions	Rheumatologist, Dermatologist, Immunologist, or Cardiologist
Coverage Duration	Initial: 4 months. 2nd Auth: 6 months. Reauth: 12 months.
Other Criteria	N/A

BERINERT

Products Affected

- Berinert

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)
Age Restrictions	N/A
Prescriber Restrictions	Allergist, Immunologist
Coverage Duration	12 months
Other Criteria	N/A

BESREMI

Products Affected

- Besremi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

BOTULINUM A TOXIN

Products Affected

- Botox
- Dysport
- Myobloc
- Xeomin

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Use for cosmetic purposes (e.g., wrinkles)
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of positive clinical response to therapy with treatment. At least 3 months have elapsed since the last treatment.

BRONCHITOL

Products Affected

- Bronchitol

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

CABLIVI

Products Affected

- Cablivi

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

CAMZYOS

Products Affected

- Camzyos

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of obstructive hypertrophic cardiomyopathy (HCM). Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain). Patient has a left ventricular ejection fraction of greater than or equal to 55%. Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation. Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: a) non-vasodilating beta blocker (e.g., bisoprolol, propranolol) and b) calcium channel blocker (e.g., verapamil, diltiazem).
Age Restrictions	N/A
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a cardiologist.
Coverage Duration	Initial: 16 weeks, Reauth: 12 months
Other Criteria	Reauthorization: Documentation of positive clinical response to therapy (e.g., improved symptom relief). Patient has a left ventricular ejection fraction of greater than or equal to 50%.

CARBAGLU

Products Affected

- Carglumic Acid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CAYSTON

Products Affected

- Cayston

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

CERDELGA

Products Affected

- Cerdelga

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

CEREZYME

Products Affected

- Cerezyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme Assay demonstrating deficiency of beta-glucocerebrosidase enzyme activity. For long-term ERT in pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher Disease that results in one or more of the following: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CHENODAL

Products Affected

- Chenodal

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Pregnancy (X), Liver Dysfunction, Bile Duct abnormalities, Nonvisualizing Gallbladder after 2 single doses of dye, Radiopaque stones, Gallstone complications requiring surgery
Required Medical Information	Ultrasonograms, stone description, LFTs, reason why patient is not a candidate for surgery, Trial and failure, contraindication, or intolerance to Ursodiol
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist
Coverage Duration	Initial: 6 months, Reauth: 6 months if condition warrants continuation
Other Criteria	N/A

CHOLBAM

Products Affected

- Cholbam

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

CHORIONIC GONADOTROPINS

Products Affected

- Chorionic Gonadotropin INJ
- Novarel
- Pregnyl
- Pregnyl W/diluent Benzyl Alcohol/nacl

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Diagnosis or use in ovulation induction
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Prior authorization is required to ensure appropriate Part D use.

CIMZIA

Products Affected

- Cimzia

- Cimzia Starter Kit

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Ankylosing Spondylitis (AS)(Initial): Diagnosis of active ankylosing spondylitis. One of the following: A) Trial/failure, contraindication, or intolerance to TWO of the following: 1) Cosentyx (secukinumab), 2) Enbrel (etanercept), 3)Humira (adalimumab), 4) Xeljanz/Xeljanz XR (tofacitinib) OR B) For continuation of prior therapy if within the past 120 days. Crohn's (CD)(Initial): Diagnosis of moderately to severely active Crohn's disease 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). One of the following: A) Trial/failure, contraindication or intolerance to BOTH Humira (adalimumab) AND Stelara (ustekinumab), OR B) For continuation of prior therapy if within the past 120 days. Non-Radiographic Axial Spondyloarthritis (NR-AXSPA)(Initial): Diagnosis of non-radiographic axial spondyloarthritis, patient has signs of inflammation, 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)(Initial): Diagnosis of 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, AND One of the following: A) Trial/failure, contraindication, or intolerance to TWO of the following: 1) Cosentyx (secukinumab), 2) Enbrel (etanercept), 3) Humira (adalimumab), 4) Otezla, 5) Skyrizi (risankizumab), 6) Stelara (ustekinumab), OR B) For continuation of prior therapy if within the past 120 days.
Age Restrictions	18 years or older

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Prescriber Restrictions	Prescribed by or in consultation with a Dermatologist, Gastroenterologist, or Rheumatologist
Coverage Duration	12 months
Other Criteria	<p>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) Humira (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. Rheumatoid Arthritis (RA): Diagnosis of active RA or moderately to severely active RA. One of the following: A) Trial/failure, contraindication, or intolerance to TWO of the following: 1) Enbrel (etanercept), 2) Humira (adalimumab), 3) Orencia, 4) Rinvoq (upadacitinib), 5) Xeljanz/Xeljanz XR (tofacitinib) OR B) For continuation of prior therapy if within the past 120 days.</p> <p>(Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline.</p>

CINRYZE

Products Affected

- Cinryze

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)
Age Restrictions	N/A
Prescriber Restrictions	Allergist, Immunologist
Coverage Duration	12 months
Other Criteria	N/A

COSELA

Products Affected

- Cosela

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of extensive-stage small cell lung cancer (ES-SCLC). Patient is receiving one of the following anti-cancer chemotherapeutic regimens: platinum/etoposide-containing regimen or topotecan-containing regimen. Infusion is completed within 4 hours prior to the start of chemotherapy. The interval between doses on sequential days will not be greater than 28 hours.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	6 months
Other Criteria	N/A

COSENTYX

Products Affected

- Cosentyx

- 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
Age Restrictions	(ERA): 4 years or older. (PSA): 2 years or older. (PSO): 6 years or older. All other indications: 18 years or older.

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Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist or Dermatologist
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline.

CRESEMBA

Products Affected

- Cresemba

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

CRINONE

Products Affected

- Crinone

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	All indications: excluded if for fertility uses.
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CRYSVITA

Products Affected

- Crysvisa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of X-Linked Hypophosphatemia confirmed by genetic testing or elevated serum FGF23 and one of the following: Epiphyseal plate has not fused or Epiphyseal plate has fused and patient is experiencing clinical signs/symptoms and failure, intolerance, or contraindication to treatment with calcitriol in combination with an oral phosphate agent. Documented fasting serum Phos level below normal range for age
Age Restrictions	1 year or older
Prescriber Restrictions	Endocrinologist or Specialist experienced in the treatment of Metabolic Bone Disorders
Coverage Duration	Initial: 6 months. Reauth: 12 months.
Other Criteria	Reauth: Documentation of normalization of serum phosphate and a positive clinical response to therapy

CYCLOBENZAPRINE

Products Affected

- Cyclobenzaprine Hydrochloride TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically accepted Indications.
Off-Label Uses	Fibromyalgia
Exclusion Criteria	N/A
Required Medical Information	For Fibromyalgia must have trial, failure, contraindication, or intolerance to at least two of the following: duloxetine, gabapentin, pregabalin, formulary antidepressants, formulary anticonvulsants, or tramadol.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	Fibromyalgia: 12 months. All other indications: 3 months
Other Criteria	Provider must submit attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older.

CYSTADROPS

Products Affected

- Cystadrops

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

CYSTAGON

Products Affected

- Cystagon

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

CYSTARAN

Products Affected

- Cystaran

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

DALFAMPRIDINE

Products Affected

- Dalfampridine Er

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Seizures, renal impairment with a CrCL less than 50 mL/min or wheelchair bound
Required Medical Information	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.
Age Restrictions	18 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 months. Reauth: 12 months (based on therapeutic response)
Other Criteria	Pt must be ambulatory with no history of seizures

DEFERASIROX

Products Affected

- Deferasirox TBSO

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Under 2 years old, severe renal insufficiency, hepatitis, if on any other iron chelation therapy concomitantly
Required Medical Information	Covered for Transfusional Iron Overload when the patient has a Serum Ferritin level greater than 1000mcg/L and discontinuation when levels are below 500mcg/L in two consecutive months. Covered for Non-Transfusion Dependent Thalassemia Syndrome with documentation of an LIC of at least 5mg Fe/G DW and serum ferritin greater than 300mcg/L and discontinuation when levels are below 300mcg/L in two consecutive months. For all indications, patient should have documentation of auditory and ophthalmic testing prior to starting deferasirox treatment.
Age Restrictions	2 years or older
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

DEFEROXAMINE

Products Affected

- Deferoxamine Mesylate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Iron toxicity, acute, iron overload, chronic, due to transfusion-dependent anemias
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

DIACOMIT

Products Affected

- Diacomit

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

DOPTELET

Products Affected

- Doptelet

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	TPPP: 1 month. ITP: 12 months
Other Criteria	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

Products Affected

- Doxercalciferol

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

DUPIXENT

Products Affected

- Dupixent

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Atopic Dermatitis: Diagnosis of moderate to severe Atopic Dermatitis with One of the following: Involvement of at least 10% body surface area (BSA), SCORing Atopic Dermatitis (SCORAD) index value of at least 25. TF/C/I of a minimum 30-day supply (14-day supply for topical corticosteroids), to at least one of the following: Medium or higher potency topical corticosteroid, Pimecrolimus cream, Tacrolimus ointment.</p> <p>Eosinophilic Asthma: Diagnosis of moderate to severe Eosinophilic Phenotype Asthma defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter.</p> <p>Corticosteroid Dependent Asthma: Diagnosis of moderate to severe Asthma. Documentation that patient is currently dependent on oral corticosteroids for the treatment of asthma. Eosinophilic Asthma, Corticosteroid Dependent Asthma: unless contraindicated, documented concurrent use of an inhaled corticosteroid and one additional asthma controller medication (e.g. Leukotriene Receptor Antagonist, Long-Acting Beta-2 Agonist, Long-Acting Muscarinic Antagonist).</p> <p>Rhinosinusitis with Nasal Polyposis: Diagnosis of Rhinosinusitis with Nasal Polyposis. Documented trial and failure, intolerance, or contraindication to one intranasal glucocorticoid and one oral glucocorticoid. Eosinophilic Esophagitis (EoE): Diagnosis of EoE confirmed by biopsy. Patient weighs at least 40 kg. PRURIGO NODULARIS: TF/C/I to one medium or higher potency topical corticosteroid.</p>
Age Restrictions	<p>Asthma: 6 years or older. Atopic Dermatitis: 6 months or older.</p> <p>Rhinosinusitis with Nasal Polyposis: 18 years or older. EoE: 12 years or older</p>
Prescriber Restrictions	Dermatologist, Allergist, Immunologist, Pulmonologist, Otolaryngologist, Gastroenterologist

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Coverage Duration	12 months
Other Criteria	Reauth: Documentation of a positive clinical response to therapy.

ELAPRASE

Products Affected

- Elaprase

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme assay demonstrating deficiency of Iduronate 2-sulfatase enzyme activity or DNA testing
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For patients with Hunter Syndrome (MPS II)

ELELYSO

Products Affected

- Elelyso

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documented of Type 1 Gauchers Disease
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

ELITEK

Products Affected

- Elitek

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Previous reaction to Elitek, Glucose 6-Phosphate Deficiency (G6PD)
Required Medical Information	Diagnosis of cancer, elevated Uric Acid levels, Tumor Lysis Syndrome. Documentation that medication was initiated while in the hospital.
Age Restrictions	N/A
Prescriber Restrictions	Oncologist
Coverage Duration	1 month
Other Criteria	N/A

EMGALITY

Products Affected

- Emgality

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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>
Age Restrictions	ECH, MP (initial): 18 years or older.
Prescriber Restrictions	Neurologist, Headache Specialist, Pain Specialist

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Coverage Duration	ALL indications (Initial): 6 months. All indications (Reauth): 12 months.
Other Criteria	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.

EMPAVELI

Products Affected

- Empaveli

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Paroxysmal Nocturnal Hemoglobinuria (PNH) (initial): Diagnosis of PNH. Documentation that member has received meningococcal vaccination per ACIP guidelines before starting therapy with Empaveli
Age Restrictions	N/A
Prescriber Restrictions	Specialist: (Oncologist, Immunologist, Hematologist)
Coverage Duration	PNH (initial, reauth): 12 months
Other Criteria	PNH (reauth): Documentation of positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions).

ENBREL

Products Affected

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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Allergic reaction to murine proteins of humanized monoclonal antibody, patients with active infections, or latent TB
Required Medical Information	Ankylosing Spondylitis (AS): Diagnosis of active AS. TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) at maximally tolerated doses for at least a one-month trial. Polyarticular Juvenile Idiopathic Arthritis (PJIA): Diagnosis of moderately to severely active PJIA. Trial/failure, contraindication, or intolerance to one of the following disease modifying anti-rheumatic drugs (DMARDs): leflunomide, methotrexate. Psoriasis (PSO): Diagnosis of moderate to severe chronic plaque psoriasis with one of the following: Greater than or equal to 3% of BSA, Severe scalp psoriasis, Palmoplantar (i.e. palms, soles), facial, or genital involvement. Minimum duration of a 4wk TF/C/I of at least 1 top tx: 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 with one of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail. 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)
Age Restrictions	JIA: 2 years or older. Plaque Psoriasis: 4 years or older. Psoriatic Arthritis: 2 years of age or older. All other diagnoses: 18 years or older.
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist or Dermatologist
Coverage Duration	12 months

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Other Criteria	MDL for Plaque Psoriasis: 50mg twice weekly for 3 months, then 50mg once weekly. MDL for all other indications: 50mg once weekly. Reauth: documentation of positive clinical response to therapy. REAUTH: (ALL) Documentation of positive clinical response to therapy as evidenced by improvement from baseline
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EPCLUSA

Products Affected

- Epclusa

- Sofosbuvir/velpatasvir

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

EPIDIOLEX

Products Affected

- Epidiolex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

EPOETIN

Products Affected

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

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

EPOPROSTENOL

Products Affected

- Epoprostenol Sodium

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients with hypersensitivity to Prostacyclin analogs, high risk of hemorrhage (e.g. active peptic ulcers, trauma, intracranial hemorrhage), severe coronary heart disease, unstable angina, MI within the last 6 months, decompensated cardiac failure not under close medical supervision, severe arrhythmias, cerebrovascular events within the last 3 months, pulmonary hypertension caused by venous occlusive disease, pregnant patients.
Required Medical Information	Previous medications used, results of acute vasoreactivity testing
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist, Cardiologist
Coverage Duration	12 months
Other Criteria	Subject to BvD decision. For the treatment of pulmonary arterial hypertension (PAH) in patients with NYHA Class II, III, or IV symptoms and for patients who have tried and failed, intolerance or contraindication (e.g. unstable patients or those with severe right heart failure) to conventional therapies, including oral anticoagulants, diuretics, supplemental oxygen, and/or digoxin.

ESBRIET

Products Affected

- Pirfenidone

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

EXONDYS 51

Products Affected

- Exondys 51

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Excluded if member is not able to remain ambulatory (e.g. able to walk with assistance, not wheelchair dependent)
Required Medical Information	Diagnosis of Duchenne Muscular Dystrophy with confirmed mutation of the Dystrophin Gene Amenable to Exon 51 skipping
Age Restrictions	N/A
Prescriber Restrictions	Specialist in the treatment of Duchenne Muscular Dystrophy
Coverage Duration	Initial: 3 months. Reauth: 6 months.
Other Criteria	Reauth: Documentation of positive clinical response to therapy and documentation that member is still ambulatory

FABRAZYME

Products Affected

- Fabrazyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme assay demonstrating deficiency of alpha-galactosidase enzyme assay or DNA testing
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For use in patients with Fabry Disease

FINTEPLA

Products Affected

- Fintepla

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	12 months
Other Criteria	N/A

GALAFOLD

Products Affected

- Galafold

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

GATTEX

Products Affected

- Gattex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Short Bowel Syndrome with dependence on parenteral support for at least 12 months
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist
Coverage Duration	Initial: 3 months. Reauth: 6 months.
Other Criteria	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

Products Affected

- Mounjaro
- Ozempic
- 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

Products Affected

- Lanreotide Acetate
- Norditropin Flexpro
- Omnitrope
- Serostim INJ 4MG, 5MG, 6MG
- Somatuline Depot
- Somavert

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

HAEGARDA

Products Affected

- Haegarda

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)
Age Restrictions	N/A
Prescriber Restrictions	Allergist, Immunologist
Coverage Duration	12 months
Other Criteria	N/A

HARVONI

Products Affected

- Harvoni

- Ledipasvir/sofosbuvir

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

HETLIOZ

Products Affected

- Hetlitz Lq
- Tasimelton

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	N/A

HRM - ANTIHISTAMINES

Products Affected

- Diphenhydramine Hcl ELIX
- 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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	Anxiety: 12 months: All others: 3 months
Other Criteria	Provider must submit attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older.

HRM - CNS, OTHER

Products Affected

- Meprobamate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-Approved indication and the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HUMIRA

Products Affected

- Adalimumab-adaz
- Amjevita INJ 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML, 80MG/0.8ML
- Hadlima
- Hadlima Pushtouch
- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients with active infections or latent TB or symptomatic or deteriorating CHF.

Required Medical Information	<p>Ankylosing Spondylitis (AS)(Initial): Diagnosis of active AS. Minimum duration of a one-month Trial/failure, contraindication, or intolerance (TF/C/I) to one nonsteroidal anti-inflammatory drug (NSAID) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) at maximally indicated doses. Crohn's (CD): Diagnosis of moderately to severely active CD with One fo the following: frequest 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). Hidradenitis Suppurativa (HS)(Initial): Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III). Polyarticular Juvenile Idiopathic Arthritis (PJIA)(Initial): Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following disease modifying anti-rheumatic drugs (DMARDs) at maximally indicated doses: leflunomide, methotrexate. Psoriasis (PSO)(Initial): Diagnosis of moderate to severe chronic plaque psoriasis with Doc of one of the following: Greater than or equal to 3% of BSA, severe scalp psoriasis, palmoplantar (i.e., palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D anaologs (e.g., calcitriol, calcipotriend), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal Tar. Psoriatic Arthritis (PSA)(Initial): Diagnosis of active PsA with One of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail involvement.</p>
Age Restrictions	<p>Crohn's: 6 years and older. JIA and Uveitis: 2 years and older. Hidradenitis Suppurativa: 12 years and older. UC: 5 years and older. All other diagnoses: 18 years and older.</p>
Prescriber Restrictions	<p>Prescribed by or in consultation with a Rheumatologist, Dermatologist, Gastroenterologist, Ophthalmologist</p>
Coverage Duration	<p>12 months</p>

Other Criteria	<p>Rheumatoid Arthritis (RA)(Initial): Diagnosis of moderately to severely active RA with a Minimum duration of a 3-month TF/C/I to one disease modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine) at maximally indicated doses. Ulcerative Colitis (UC)(Initial): 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 . TF/C/I to a corticosteroid, immunosuppressant, or aminosalicylates (e.g. azathioprine, 6-MP, methotrexate, mesalamine, olsalazine, or azathioprine). Uveitis(Initial): Diagnosis of non-infectious uveitis and classified as intermediate, posterior, or panuveitis.</p> <p>Reauth (ALL): Documentation of positive clinical response to therapy as evidenced by improvement from baseline.</p>
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ICATIBANT

Products Affected

- Icatibant Acetate

- Sajazir

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	18 years or older
Prescriber Restrictions	Allergist, Immunologist
Coverage Duration	12 months
Other Criteria	Documentation of diagnosis of Hereditary Angioedema

ILARIS

Products Affected

- Ilaris INJ 150MG/ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	(Initial, Reauth): Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors [e.g., Enbrel (etanercept) (etanercept), Humira (adalimumab) (adalimumab), Remicade (infliximab)]. Patient is not receiving concomitant treatment with Interleukin-1 inhibitors [e.g., Arcalyst (rilonacept), Kineret (anakinra)].
Required Medical Information	Systemic Juvenile Idiopathic Arthritis (SJIA): Diagnosis of active systemic juvenile idiopathic arthritis. Documented trial/failure, contraindication, or intolerance to ONE of the following Conventional therapies at maximally indicated doses: Minimum duration of a 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen), OR Minimum duration of a 2-week trial of Corticosteroids (e.g., methylprednisolone, prednisone), OR Minimum duration of a 3-month trial and failure of Methotrexate.
Age Restrictions	2 years or older
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist
Coverage Duration	12 months
Other Criteria	Reauth: (SJIA) Documentation of positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

INCRELEX

Products Affected

- Increlex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients with closed epiphyses, patients with active or suspected neoplasia
Required Medical Information	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
Age Restrictions	2 years or older
Prescriber Restrictions	Endocrinologist
Coverage Duration	12 months
Other Criteria	Discontinuation occurs when linear growth ceases

INFLIXIMAB

Products Affected

- Avsola
- Inflectra
- Infliximab
- Remicade
- Renflexis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Ankylosing Spondylitis (AS)(Initial): Diagnosis of active AS with a minimum duration of a one-month Trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) at maximally indicated doses. Avsola, Inflectra, and Renflexis only: Trial and failure or intolerance to Remicade or Infliximab. Crohn's Disease (CD)(Initial): Diagnosis of moderately to severely active CD OR Fistulizing Crohn's disease (FCD) 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: corticosteroid or immunosuppressant (azathioprine, 6-MP, or methotrexate) therapy. Avsola, Inflectra, and Renflexis only: Trial and failure or intolerance to Remicade or Infliximab. Psoriasis (PSO)(Initial): Doc that pt has chronic sev plaque psoriasis (i.e., extensive and/or disabling) 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. Avsola, Inflectra, and Renflexis only: Trial and failure or intolerance to Remicade or Infliximab. Psoriatic Arthritis (PSA)(Initial): Diagnosis of active PSA with One of the following: Actively inflamed joints, Dactylitis, Enthesitis, Axial disease, Active skin and/or nail involvement. Avsola, Inflectra, and Renflexis only: Trial and failure or intolerance to Remicade or Infliximab.
Age Restrictions	N/A

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Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist, Gastroenterologist, Dermatologist
Coverage Duration	12 months
Other Criteria	<p>Rheumatoid Arthritis (RA)(Initial): Diagnosis of moderately to severely active RA AND used in combination with methotrexate. Avsola, Inflectra, and Renflexis only: Trial and failure or intolerance to Remicade or Infliximab. Documentation of failure to respond to a 2 month trial of Enbrel (etanercept) or Humira (adalimumab) or an intolerance of or contraindication to Enbrel (etanercept) or Humira (adalimumab). Must have concurrent treatment with MTX OR trial/failure/intolerance/contra. All dose incr after initial tx must be prior auth'd. Ulcerative Colitis (UC)(Initial): Use for 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 . Trial/failure, intolerance, or contraindication to a corticosteroid, immunosuppressant, or aminosalicylates (e.g. azathioprine, 6-MP, methotrexate, mesalamine, osalazine, sulfasalazine). Avsola, Inflectra, and Renflexis only: Trial and failure or intolerance to Remicade or Infliximab</p> <p>Reauth: (All) Documentation of positive clinical response to therapy as evidenced by improvement from baseline. All indications: TB screening</p>

INGREZZA

Products Affected

- Ingrezza

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of Tardive Dyskinesia
Age Restrictions	N/A
Prescriber Restrictions	Neurologist, Psychiatrist
Coverage Duration	12 months
Other Criteria	QL: 60 tablets per 30 days

ISTURISA

Products Affected

- Isturisa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	12 months
Other Criteria	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

Products Affected

- Ivermectin TABS

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

JAKAFI

Products Affected

- Jakafi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

JUXTAPID

Products Affected

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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	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
Required Medical Information	Diagnosis of Homozygous Familial Hypercholesterolemia, liver function tests, and negative pregnancy test in women with reproductive potential
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist, Cardiologist
Coverage Duration	Initial: 6 months. Reauth: 6 months
Other Criteria	N/A

JYNARQUE

Products Affected

- Jynarque

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

KALBITOR

Products Affected

- Kalbitor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 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 (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)
Age Restrictions	N/A
Prescriber Restrictions	Allergist, Immunologist
Coverage Duration	12 months
Other Criteria	Confirmed diagnosis of HAE and member must be experiencing at least one symptom of the moderate or severe attack (e.g. airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion).

KALYDECO

Products Affected

- Kalydeco

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

KANUMA

Products Affected

- Kanuma

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documented Diagnosis of Wolman's Disease
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist, Geneticist, Gastroenterologist, Lipidologist, Metabolic Specialist
Coverage Duration	12 months
Other Criteria	N/A

KEPIVANCE

Products Affected

- Kepivance

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients with non-hematologic malignancies
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Oncologist
Coverage Duration	3 months
Other Criteria	Subject to BvD decision.

KERENDIA

Products Affected

- Kerendia

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 ² , 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 ² . 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	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.

KEVEYIS

Products Affected

- Dichlorphenamide

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documented Diagnosis of Primary Hyperkalemic Periodic Paralysis or Primary Hypokalemic Periodic Paralysis, or Related Variants of Primary Paralysis
Age Restrictions	N/A
Prescriber Restrictions	Neurologist, Endocrinologist
Coverage Duration	Initial: 3 months. Reauth: 12 months (with documentation of beneficial response)
Other Criteria	N/A

KINERET

Products Affected

- Kineret

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Hypersensitivity to proteins derived from E. coli
Required Medical Information	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), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), OR B) For continuation of prior therapy if within the past 120 days.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist, Dermatologist, Neurologist, Pediatrician
Coverage Duration	12 months
Other Criteria	Reauth: (All) Documentation of positive clinical response to therapy as evidenced by improvement from baseline.

KORLYM

Products Affected

- Korlym
- Mifepristone TABS 300MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	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
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

KRYSTEXXA

Products Affected

- Krystexxa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Anaphylaxis and infusions reactions (boxed warning), contraindication in pt w/G6PD deficiency due to risk of hemolysis and methemoglobinemia, Gout flares during initiation of treatment
Required Medical Information	Documentation of Chronic Gout in adult patients refractory to conventional therapy and 3 month trial of XO Inhibitor (e.g. allopurinol, febuxostat).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

KUVAN

Products Affected

- Sapropterin Dihydrochloride

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	Initial: 2 months. Reauth: 3 months
Other Criteria	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.

LEMTRADA

Products Affected

- Lemtrada

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (e.g. Relapsing-Remitting MS, Secondary-Progressive MS with relapses, Progressive-Relapsing MS with relapses). One of the following: 1) Patient has not been previously treated with alemtuzumab, and patient has had at least a 4 week trial and failure, contraindication, or intolerance to two of the following: Interferon Beta-1A (Avonex or Rebif), Interferon Beta-1B (Betaseron, Extavia), glatiramer acetate (Copaxone or Glatopa), dimethyl fumarate (Tecfidera), teriflunomide (Aubagio), fingolimod (Gilenya), peginterferon Beta-1A (Plegridy), Natalizumab (Tysabri) or 2) Patient has previously received treatment with alemtuzumab, and at least 12 months have or will have elapsed since the first treatment with alemtuzumab, and patient has not already received the FDA-recommended lifetime limit of two treatment courses of alemtuzumab. Patient is not receiving alemtuzumab in combination with another disease modifying agent (e.g. interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, or teriflunomide).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MS: 12 months. Max: 24 months.
Other Criteria	N/A

LEUKINE

Products Affected

- Leukine INJ 250MCG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concomitant use with chemotherapy or radiotherapy or use within 24 hours
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Subject to BvD decision. Allogenic bone marrow transplantation, myeloid reconstitution in HLA-matched related donors, Autologous bone marrow transplantation, myeloid reconstitution following transplant in patients with Non-Hodgkin's Lymphoma, Hodgkin's Disease, and Acute Lymphoblastic Leukemia, bone marrow transplant, delay or failure of myeloid engraftment, febrile neutropenia, in acute myelogenous leukemia following induction chemotherapy, prophylaxis harvesting of peripheral blood stem cells, peripheral blood stem cell graft, autologous, myeloid reconstitution following transplant in patients mobilized with granulocyte macrophage colony stimulating factor.

LEUPROLIDE

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)
- Lupron Depot-ped (3-month)
- 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

Products Affected

- Lidocaine PTCH 5%

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

LUMIZYME

Products Affected

- Lumizyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme testing that demonstrates reduced GAA enzyme activity or by DNA testing for mutations in the GAA gene.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

LUPKYNIS

Products Affected

- Lupkynis

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

MAVENCLAD

Products Affected

- Mavenclad

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	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)
Required Medical Information	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
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months, max 24 months
Other Criteria	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

Products Affected

- Mavyret

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

MEGACE

Products Affected

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

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	Evaluate use as a Part D covered diagnosis

MOZOBIL

Products Affected

- Mozobil
- Plerixafor

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	1 month
Other Criteria	Subject to BvD decision. Harvesting of peripheral blood stem cells, in patients with Non-Hodgkin's Lymphoma and Multiple Myeloma.

MULPLETA

Products Affected

- Mulpleta

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

MYALEPT

Products Affected

- Myalept

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	HIV related lipodystrophy, metabolic disease without current evidence of generalized lipodystrophy.
Required Medical Information	Diagnosis of Congenital or Acquired Generalized Lipodystrophy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

NAGLAZYME

Products Affected

- Naglazyme

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme assay demonstrating deficiency of N-acetylgalactosamine 4-sulfatase (Arylsulfatase B) enzyme activity or DNA testing
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For patients with MPS VI

NATPARA

Products Affected

- Natpara

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of Hypocalcemia due to Hypoparathyroidism, and documented trial and failure, contraindication, or intolerance to calcitriol
Age Restrictions	18 years or older
Prescriber Restrictions	Endocrinologist
Coverage Duration	6 months
Other Criteria	N/A

NEXLETOL

Products Affected

- Nexletol

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Nexletol will not be covered in combination concomitant use with PCSK9 therapy
Required Medical Information	Documented diagnosis of established Atherosclerotic Cardiovascular Disease or Heterozygous Familial Hypercholesterolemia
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Documented inability to achieve LDL-C goals on maximally tolerated statin therapy

NEXLIZET

Products Affected

- Nexlizet

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Nexlizet will not be covered in combination concomitant use with PCSK9 therapy
Required Medical Information	Documented diagnosis of established Atherosclerotic Cardiovascular Disease or Heterozygous Familial Hypercholesterolemia
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Documented inability to achieve LDL-C goals on maximally tolerated statin therapy

NUCALA

Products Affected

- Nucala

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of Eosinophilic Phenotype Severe Asthma. Peripheral Blood Eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks. Documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA). Documented diagnosis of hypereosinophilic syndrome (HES). Documented diagnosis of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP).
Age Restrictions	6 years or older
Prescriber Restrictions	Allergist, Immunologist, Pulmonologist, Rheumatologist, Hematologist, Otolaryngologist
Coverage Duration	12 months
Other Criteria	Asthma: Documented concurrent use of an inhaled corticosteroid, and documented concurrent use of one of the following: Inhaled Long Acting Beta Agonist (Serevent, Foradil), Long Acting Anti-Muscarinic Antagonist (Tudorza, Spiriva), Leukotriene Receptor Antagonist (montelukast, zafirlukast), theophylline. EGPA: Documented failure of oral glucocorticoids.

NUEDEXTA

Products Affected

- Nuedexta

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

NUPLAZID

Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Parkinson's Disease- Psychotic Disorder
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	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-HT ₁ 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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Prescriber Restrictions	Neurologist, Pain Specialist, Headache Specialist or Physician who specializes in the treatment of Chronic Migraine Management
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Documentation of positive clinical response to therapy (reduction in pain, photophobia, phonophobia).

NUVIGIL

Products Affected

- Armodafinil

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Treatment of Multiple Sclerosis
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Primary Biliary Cirrhosis used in combo with ursodeoxycholic acid or as monotherapy when ursodeoxycholic acid is not tolerated
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

OCTREOTIDE

Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of Acromegaly with inadequate response to surgery or resection is not an option or inadequate response to radiation or failed bromocriptine or adjunctive tx w irradiation to help relieve sx's and possibly slow tumor growth, prophylactic treatment prior to surgery for gastrinoma
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

OFEV

Products Affected

- Ofev

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist
Coverage Duration	12 months
Other Criteria	N/A

ONCOLOGY AGENTS

Products Affected

- Abiraterone Acetate
- Adstiladrin
- Akeega
- Alecensa
- Alimta
- Aliqopa
- Alunbrig
- Alymsys
- Augtyro
- Ayvakit
- Balversa
- Bavencio
- Beleodaq
- Bendamustine Hydrochloride
- Bendeka
- Besponsa
- Bexarotene CAPS
- Blincyto
- Bortezomib
- Bosulif
- Braftovi CAPS 75MG
- Brukinsa
- Cabometyx
- Calquence
- Caprelsa
- Columvi
- Cometriq
- Copiktra
- Cotellic
- Cyramza
- Dactinomycin
- Danyelza
- Darzalex
- Darzalex Faspro
- Daurismo
- Elahere
- Elrexio
- Elzonris
- Empliciti
- Enhertu
- Epkinly
- Erbitux
- Erivedge
- Erleada
- Erlotinib Hydrochloride TABS
- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO
- Evomela
- Exkivity
- Fotivda
- Fruzaqla
- Fyarro
- Gavreto
- Gazyva
- Gefitinib
- Gilotrif
- Herceptin INJ 150MG
- Herceptin Hylecta
- Herzuma
- Ibrance
- Iclusig
- Idhifa
- Imatinib Mesylate
- Imbruvica
- Imfinzi
- Imjudo
- Infugem
- Inlyta
- Inqovi
- Inrebic
- Iwifin
- Jaypirca
- Jemperli
- Kanjinti
- Keytruda INJ 100MG/4ML
- Kimmtrak
- Kisqali
- Kisqali Femara 200 Dose

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- 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
- Libtayo
- Lonsurf
- Loqtorzi
- Lorbrina
- Lumakras
- Lumoxiti
- Lunsumio
- Lynparza TABS
- Lytgobi
- Margenza
- Matulane
- Mekinist
- Mektovi
- Melphalan Hydrochloride
- Monjuvi
- Mvasi
- Mylotarg
- Nerlynx
- Ninlaro
- Nubeqa
- Odomzo
- Ogivri INJ 1.1%; 420MG, 150MG
- Ogsiveo
- Ojjaara
- Ontruzant
- Opdivo
- Opdualag
- Orgovyx
- Orserdu
- Padcev
- Pazopanib Hydrochloride
- Pemazyre
- Pemetrexed
- Pemetrexed Disodium
- Pemfexy
- Pemrydi Rtu
- Perjeta
- Phesgo
- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose
- Polivy
- Pomalyst
- Portrazza
- Qinlock
- Retevmo
- Revlimid
- Rezlidhia
- Riabni
- Rituxan
- Rituxan Hycela
- Rozlytrek
- Rubraca
- Ruxience
- Rybrevant
- Rydapt
- Sarclisa
- Scemblix
- Sorafenib
- Sorafenib Tosylate TABS
- Sprycel
- Stivarga
- Sunitinib Malate
- Sylvant
- Tabloid
- Tabrecta
- Tafenlar
- Tagrisso
- Talvey
- Talzena
- Tasigna
- Tazverik

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- Tecentriq
- Tecvayli
- Temodar INJ
- Tepmetko
- Thiotepa INJ 100MG, 15MG
- Tibsovo
- Tivdak
- Toremifene Citrate
- Trazimera
- Treanda INJ 100MG, 25MG
- Trelstar Mixject
- Tretinoin CAPS
- Trodelvy
- Truqap
- Truseltiq
- Truxima
- Tukysa
- Turalio
- Vanflyta
- Vectibix INJ 100MG/5ML, 400MG/20ML
- Vegzelma
- Velcade
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Vitrakvi
- Vizimpro
- Vonjo
- Votrient
- Vyxeos
- Welireg
- Xalkori
- Xospata
- Xpovio
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly
- Xtandi
- Yervoy
- Yondelis
- Yonsa
- Zejula
- Zelboraf
- Zepzelca
- Zoladex
- Zolanza
- Zydelig
- Zykadia TABS
- Zynlonta
- Zynyz

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For requests of brand agents within this policy that have a generic available, must have trial/failure of generic agent first
Age Restrictions	N/A

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Prescriber Restrictions	Ayvakit: Prescribed by or in consultation with an oncologist/hematologist, allergist, or immunologist. All others: Oncologist, Hematologist, Rheumatologist, Transplant Specialist, Neurologist
Coverage Duration	12 months
Other Criteria	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).

OPSUMIT

Products Affected

- Opsumit

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

ORAL FENTANYL PRODUCTS

Products Affected

- Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

ORENCIA

Products Affected

- Orencia
- Orencia Clickject

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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), Humira (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)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist or Dermatologist
Coverage Duration	12 months
Other Criteria	Reauth: (All) Documentation of positive clinical response to therapy as evidenced by improvement from baseline.

ORFADIN

Products Affected

- Nitisinone
- Orfadin SUSP

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Confirmed by biochemical testing (e.g. detection of succinylacetone in urine) and appropriate clinical picture of the patient or by DNA testing
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Orfadin (nitisinone) is indicated in the treatment of patients with Hereditary Tyrosinemia Type 1 (HT-1)

ORKAMBI

Products Affected

- Orkambi

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

ORLADEYO

Products Affected

- Orladeyo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	12 months
Other Criteria	N/A

OSPHERA

Products Affected

- OspheNa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Dyspareunia and vaginal dryness (Reauth): Documentation of positive clinical response to therapy

OTEZLA

Products Affected

- Otezla

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Behcet Disease: Diagnosis of Behcet Disease with oral ulcers. Trial and failure, intolerance, or contraindication to colchicine. Psoriasis (PSO): Diagnosis of moderate to severe plaque psoriasis with One of the following: Greater than or equal to 2% body surface area involvement, Severe scalp psoriasis, Palmoplantar (i.e., palms, soles), facial, or genital involvement. 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.
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist or Dermatologist
Coverage Duration	12 months
Other Criteria	Reauth: (All) Documentation of positive clinical response to therapy as evidenced by improvement from baseline.

OXANDROLONE

Products Affected

- Oxandrolone TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Carcinoma of the breast in females with hypercalcemia, Carcinoma of the prostate or the male breast, Hypercalcemia, Nephrosis, Pregnancy.
Required Medical Information	Steps taken to avoid weight loss. Documentation of a hx of a failure to gain weight. Hx of extensive surgery, chronic infections, severe trauma, or other pathophysiological reasons for a failure to gain or maintain weight. Hx of corticosteroid use or dx of osteoporosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	Documentation of a hx of failure to gain weight due to a hx of extensive surgery, chronic infections, severe trauma, or other pathophysiological reasons for failure to gain or maintain weight or hx of long-term corticosteroid use of bone pain associated with osteoporosis.

OXERVATE

Products Affected

- Oxervate

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)
Age Restrictions	N/A
Prescriber Restrictions	Ophthalmologist
Coverage Duration	8 weeks
Other Criteria	Reauth: Documentation of recurrence of neurotrophic keratitis

PART D Vs. EXCLUDED

Products Affected

- Glydo
- Imvexxy Maintenance Pack
- Imvexxy Starter Pack
- Lidocaine OINT 5%
- Lidocaine Hcl PRSY
- Lidocaine Hcl Jelly
- Lidocaine Hydrochloride EXTERNAL SOLN
- Lidocaine/prilocaine CREA
- Pliaglis 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

PH PDE5 INHIBITORS

Products Affected

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

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

PRETOMANID

Products Affected

- Pretomanid

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

PROCYSBI

Products Affected

- Procysbi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Documented allergy to penicillamine
Required Medical Information	Nephropathic Cystinosis: Diagnosis of Nephropathic Cystinosis, confirmed by elevated Leukocyte Cystine Levels (LCL) or genetic analysis of the CTNS Gene or demonstration of Cysteine Corneal Crystals by slit lamp examination.
Age Restrictions	1 year or older
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: 6 months with documentation of WBC cystine levels
Other Criteria	Documentation of trial and failure of max rec dose of Cysteamine IR caps. Adolescents weighing more than 50kg, adults 1.95G/M2/Day. Doc of WBC Cystine levels greater than 1nmol half-cystine/mg protein

PROMACTA AND NPLATE

Products Affected

- Nplate
- Promacta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Coverage excluded if intent is to solely normalize platelet counts
Required Medical Information	Documentation of an insufficient response or contraindications to first line therapies of immune idiopathic thrombocytopenic purpura, (e.g. corticosteroids or, immunoglobulins, or splenectomy) or if clinical condition increases the risk for bleeding. Promacta will also be covered for thrombocytopenia in pts w/chronic hep C. Diagnosis of SAA. Used for first-line treatment (e.g., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy. Patient meets at least two of the following: 1) Absolute neutrophil count less than 500/mcl, 2) Platelet count less than 20,000/mcl, 3) Absolute reticulocyte count less than 60,000/mcl. Refractory SAA: Diagnosis of Refractory Severe Aplastic Anemia. Patient has a platelet count less than 30,000/mcl. Insufficient response to immunosuppressive therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A

PROVIGIL

Products Affected

- Modafinil TABS

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Treatment of Multiple Sclerosis
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	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

Products Affected

- Pulmozyme SOLN 2.5MG/2.5ML

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	Pulmonologist
Coverage Duration	12 months
Other Criteria	Subject to BvD decision. Diagnosis of Cystic Fibrosis.

QUALAQUIN

Products Affected

- Quinine Sulfate CAPS 324MG

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	6 months
Other Criteria	Prior authorization to ensure use for malaria

RAVICTI

Products Affected

- Ravicti

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

REBLOZYL

Products Affected

- Reblozyl

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Hemoglobin (sickle) s/beta thalassemia or alpha thalassemia (e.g. hemoglobin H)
Required Medical Information	Diagnosis of beta-thalassemia or hemoglobin e/beta-thalassemia (may include beta-thalassemia with mutation and/or multiplication of alpha globin)
Age Restrictions	18 years or older
Prescriber Restrictions	Hematologist
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	N/A

REGRANEX

Products Affected

- Regranex

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

RELISTOR

Products Affected

- Relistor

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	3 months
Other Criteria	Requires trial and failure of standard laxative therapy (docusate, senna, polyethylene glycol (Miralax), magnesium citrate, etc.). Continuation of therapy requires documentation of improvement

REYVOW

Products Affected

- Reyvow

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Reyvow will not be approved if being used in combination with Nurtec (rimegepant) or Ubrelvy (ubrogepant)
Required Medical Information	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 ergot type 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
Age Restrictions	18 years or older
Prescriber Restrictions	Neurologist, Pain Specialist, Headache Specialist or Physician who specializes in the treatment of Chronic Migraine Management
Coverage Duration	Initial: 12 months. Reauth: 12 months (with documentation of beneficial response).
Other Criteria	Reauth: Documentation of positive clinical response to therapy (reduction in pain, photophobia, phonophobia)

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REZUROCK

Products Affected

- Rezurock

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.).
Age Restrictions	N/A
Prescriber Restrictions	cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients.
Coverage Duration	cGVHD (initial, reauth): 12 months
Other Criteria	cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.

RIBAVIRIN ORAL INHALATION

Products Affected

- Ribavirin SOLR

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Hypersensitivity to ribavirin or any component of the product, Pregnant women or women who may become pregnant during treatment.
Required Medical Information	Confirmed dx of RSV infection
Age Restrictions	N/A
Prescriber Restrictions	Immunologist, Infectious Disease Specialist, Pulmonologist
Coverage Duration	1 month
Other Criteria	Subject to BvD decision. Hospitalization due to RSV infection.

RINVOQ

Products Affected

- Rinvoq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (e.g., azathioprine, cyclosporine)
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, AND patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel, Humira). Atopic Dermatitis (AD)(Initial)(15 and 30mg): Diagnosis of moderate to severe atopic dermatitis, with One of the following: Involvement of at least 10% body surface area (BSA), SCORing Atopic Dermatitis (SCORAD) index value of at least 25. AND A TF/C/I minimum 30-day supply (14-day supply for topical corticosteroids) on: Medium or higher potency topical corticosteroid, Pimecrolimus cream, Tacrolimus ointment. AND One of the following: Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.), OR Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies: Adbry (tralokinumab-ldrm), Dupixent (dupilumab). 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.
Age Restrictions	12 years or older

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Prescriber Restrictions	Prescribed by or in consultation with an Allergist, Dermatologist, Gastroenterologist, Immunologist, Rheumatologist
Coverage Duration	12 months
Other Criteria	<p>Psoriatic Arthritis (PsA)(Initial)(15mg): 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 Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel (etanercept), Humira (adalimumab)).</p> <p>Rheumatoid Arthritis (RA)(Initial)(15mg): 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) at maximally tolerated doses, AND Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel (etanercept), Humira (adalimumab)).</p> <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 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), AND patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Humira). (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline.</p>

RUCONEST

Products Affected

- Ruconest

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

SAMSCA

Products Affected

- Tolvaptan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	To raise Serum Na urgently to prevent or to treat serious neurological symptoms
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	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

SIGNIFOR

Products Affected

- Signifor
- Signifor Lar

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Endocrinologist
Coverage Duration	Initials: 3 months. Reauth: 12 months.
Other Criteria	N/A

SIRTURO

Products Affected

- Sirturo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Diagnosis of latent infection due to mycobacterium, extrapulmonary or drug sensitive TB or Non-TB mycobacterial infection
Required Medical Information	Multi-Drug resistant TB with confirmed susceptibility data that indicate member has pulmonary MDR-TB
Age Restrictions	N/A
Prescriber Restrictions	Infectious Disease Specialist
Coverage Duration	24 weeks
Other Criteria	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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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>
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a Dermatologist, Rheumatologist, or Gastroenterologist
Coverage Duration	12 months

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Other Criteria	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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SOLIRIS

Products Affected

- Soliris

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of pt having had a meningococcal vaccination at least 2 weeks prior to administration
Age Restrictions	N/A
Prescriber Restrictions	Oncologist, Hematologist
Coverage Duration	1 month
Other Criteria	Subject to BvD decision.

SOVALDI

Products Affected

- Sovaldi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Chronic Hepatitis C. Criteria will be applied consistent with current AASLD-IDSA guidance
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Coverage duration will follow recommendation set forth by the AASLD
Other Criteria	Genotype 1 must have trial and failure with Harvoni or Viekira Pak prior to Sovaldi

SPRAVATO

Products Affected

- Spravato 56mg Dose
- Spravato 84mg Dose

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: A) Both of the following: 1) Diagnosis of major depressive disorder (treatment-resistant) and 2) Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode OR B) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has both of the following: a) depressive symptoms and b) acute suicidal ideation or behavior. Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

STELARA

Products Affected

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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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>
Age Restrictions	Psoriatic Arthritis: 6 years or older. Plaque Psoriasis: 6 years or older.

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

STRENSIQ

Products Affected

- Strensiq

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of Juvenile-Onset Hypophosphatasia or Perinatal or Infant-Onset Hypophosphatasia
Age Restrictions	N/A
Prescriber Restrictions	Geneticist, Endocrinologist, Metabolist Specialist
Coverage Duration	12 months
Other Criteria	N/A

SUB-Q IG

Products Affected

- Cuvitru
- Hizentra

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of primary immunodeficiency is the only covered indication for subcutaneous route
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Subject to BvD decision. Not to be given in conditions such as ITP and neuropathies in which large doses are usually given to block FC receptor function, complement deposition or other immunomodulatory effects.

SUCRAID

Products Affected

- Sucraid

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

SUNOSI

Products Affected

- Sunosi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

SYMDEKO

Products Affected

- Symdeko

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	6 years or older
Prescriber Restrictions	Pulmonologist
Coverage Duration	12 months
Other Criteria	N/A

SYMLIN

Products Affected

- Symlinpen 120
- Symlinpen 60

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	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.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Failure to achieve adequate glycemic control for adults who take mealtime insulin

SYNAGIS

Products Affected

- Synagis INJ 100MG/ML, 50MG/0.5ML

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	Children less than 2 years
Prescriber Restrictions	Pediatrician, Pediatric Pulmonologist, Cardiologist, Neurologist
Coverage Duration	RSV season as defined annually by the CDC.
Other Criteria	Infants less than 12 months born before 29 weeks gestation or those with Congenital Heart Disease, CLD or other chronic illness. 12-24 months who needed sup O2 for 28 days+ after birth and continue to need med intervention (sup O2, chronic corticosteroid or diuretic tx). Children greater than 24 months if profoundly immunocompromised during RSV season

TADALAFIL ONCE DAILY

Products Affected

- Tadalafil TABS 2.5MG, 5MG

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Erectile dysfunction or concurrent use of nitrates
Required Medical Information	Documentation of benign prostatic hyperplasia. Patient has experienced intolerance to or treatment failure with an alpha-blocker (e.g. doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g. finasteride)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TAFAMIDIS

Products Affected

- Vyndamax
- Vyndaqel

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	All FDA- Approved indications: Amyloid cardiomyopathy (ATTR-CM) with TTR mutation or amyloid deposits
Age Restrictions	N/A
Prescriber Restrictions	Cardiologist
Coverage Duration	12 months
Other Criteria	N/A

TAKHZYRO

Products Affected

- Takhzyro

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

TALTZ

Products Affected

- Taltz

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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) Humira (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) Humira (adalimumab), 4) Otezla, 5) Skyrizi (risankizumab), 6) Stelara (ustekinumab) OR B) For continuation of prior therapy if within the past 120 days.
Age Restrictions	PSO: 6 years or older, All others: 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist or Dermatologist
Coverage Duration	12 months

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Other Criteria	<p>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:</p> <p>A) Trial/failure, contraindication, or intolerance to TWO of the following: 1) Cosentyx (secukinumab), 2) Enbrel (etanercept) , 3) Humira (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.</p> <p>(Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline.</p>
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TARGRETIN

Products Affected

- Bexarotene GEL

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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]).
Age Restrictions	N/A
Prescriber Restrictions	Oncologist, Dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

TAZORAC

Products Affected

- Tazarotene CREA
- Tazarotene GEL
- Tazorac CREA 0.05%

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Coverage of tazarotene requires a documented condition other than cosmetic/photo aging.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TCAS

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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Provider must submit attestation that benefit outweighs risk of drugs found to be high risk medications for beneficiaries age 65 and older
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Prior authorization is not required for anyone under the age of 65

TERIPARATIDE

Products Affected

- Forteo INJ 600MCG/2.4ML

- Teriparatide

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patients who are at an increased risk of osteosarcoma, including those with Paget's Disease, unexplained elevations in serum alkaline phosphatase, prior skeletal radiation, or in children or young adults with open epiphyses
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (initial): 24 months. All uses (reauth): 12 months.
Other Criteria	For the tx of postmenopausal women with osteoporosis or to increase bone mass in men with primary hypogonadal osteoporosis or for the tx of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5mg or greater of prednisone) who are at high risk for fracture. High risk defined as a history of osteoporotic fracture, multiple risk factors for fracture, or pts who are intolerant to or have had failure to increase bone mass density after 6 months to 1 year tx with a bisphosphonate (in females)

TESTOSTERONE REPLACEMENT

Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of male with hypogonadism with total serum testosterone less than 300ng/dL w/in 90 days or documentation of male with delayed puberty not secondary to pathological disorder or documentation of female with metastatic breast cancer
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Danazol will also be covered for the following indications: endometriosis, fibrocystic breast disease and hereditary angioedema

TETRABENAZINE

Products Affected

- Tetrabenazine

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

TEZSPIRE

Products Affected

- Tezspire

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of severe asthma, Age 12 years or older, Documented concurrent use of an inhaled corticosteroid (ICS) and one additional asthma controller medication (LABA, LAMA, or leukotriene modifier) with lack of asthma control. For patients with eosinophilic asthma, documentation of trial, failure, or contraindication to Dupixent
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	12 months
Other Criteria	Reauth: documentation of beneficial therapy

THALOMID

Products Affected

- Thalomid

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

TOBRAMYCIN

Products Affected

- Tobramycin NEBU 300MG/5ML
- Tobi Podhaler

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

TREPROSTINIL

Products Affected

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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of results of acute vasoreactivity testing
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist, Cardiologist
Coverage Duration	12 months
Other Criteria	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.

TREPROSTINIL IV BvD

Products Affected

- Remodulin
- Treprostinil
- Tyvaso
- Tyvaso Refill
- Tyvaso Starter

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Previous medications used, results of acute vasoreactivity testing
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist, Cardiologist
Coverage Duration	12 months
Other Criteria	Subject to BvD decision. 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

Products Affected

- Avita
- Azelex
- Tretinoin CREA
- Tretinoin GEL
- Tretinoin Microsphere GEL 0.04%, 0.1%
- Tretinoin Microsphere Pump

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

TRIKAFTA

Products Affected

- Trikafta

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of Cystic fibrosis and documentation that member has at least one F508del mutation in the CFTR gene
Age Restrictions	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.
Prescriber Restrictions	Pulmonologist
Coverage Duration	12 months
Other Criteria	N/A

TYSABRI

Products Affected

- Tysabri

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of moderate to severe Crohn's with inadequate response or unable to tolerate treatment with Humira (adalimumab) or documentation of relapsing forms of MS
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ULTOMIRIS

Products Affected

- Ultomiris INJ 1100MG/11ML, 300MG/3ML

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Ultomiris cannot be used in combination with another terminal complement inhibitor, such as Soliris (eculizumab), Ultomiris cannot be used in patients with Shiga Toxin E. Coli related Hemolytic Uremic Syndrome (STEC-HUS)
Required Medical Information	Documentation of one of the following diagnoses: Paroxysmal nocturnal hemoglobinuria (PNH) and age 18 years or older, or Atypical hemolytic uremic syndrome (aHUS) and age 1 month or older
Age Restrictions	N/A
Prescriber Restrictions	Prescriber in the Ultomiris REMS Program
Coverage Duration	12 months
Other Criteria	Reauth: 12 months based on documentation of positive clinical response to therapy (e.g. improvement in hemolytic parameters and/or improvement in clinical symptoms)

UPTRAVI

Products Affected

- Uptravi
- Uptravi Titration Pack

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

VALCHLOR

Products Affected

- Valchlor

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of treatment of Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs) in patients who have received prior skin-directed therapy
Age Restrictions	18 years or older
Prescriber Restrictions	Oncologist
Coverage Duration	6 months
Other Criteria	N/A

VASCEPA

Products Affected

- Icosapent Ethyl
- Vascepa CAPS 0.5GM

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Severe Hypertriglyceridemia: Dx of hypertriglyceridemia and patient has a pre-treatment triglyceride (TG) level greater than or equal to 500mg/dl. Prevent of CV events: Dx of hypertriglyceridemia and patient has a pre-treatment TG level of 150 to 499mg/dl. One of the following: 1) Patient has established cardiovascular disease (CVD) (e.g. coronary artery disease, cerebrovascular or carotid disease, peripheral artery disease, etc.), or 2) Both of the following: A) Dx of diabetes mellitus and B) Patient has two or more risk factors for developing CVD. Medication will be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Severe Hypertriglyceridemia (Reauth): Documentation of positive clinical response to therapy. Prevention of CV events (Reauth): Documentation of positive clinical response to therapy. Medication continues to be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy.

VENTAVIS

Products Affected

- Ventavis

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Previous medications used, results of acute vasoreactivity testing
Age Restrictions	N/A
Prescriber Restrictions	Pulmonologist, Cardiologist
Coverage Duration	12 months
Other Criteria	Subject to BvD decision. For the treatment of pulmonary arterial hypertension (PAH) in patients with NYHA Class II, III, or IV symptoms and positive clinical response to therapy, and trial and failure of oral calcium channel blockers if acute vasoreactivity testing is positive or unless contraindicated (e.g. unstable patients or those with severe right heart failure).

VERQUVO

Products Affected

- Verquvo

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of positive clinical response to therapy as evidenced by improvement from baseline

VIBERZI

Products Affected

- Viberzi

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist
Coverage Duration	12 months
Other Criteria	N/A

VIMIZIM

Products Affected

- Vimizim

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Documentation of mucopolysaccharidosis Type IV A (MPS IV A Morquio A Syndrome)
Age Restrictions	5 years or older
Prescriber Restrictions	Geneticist
Coverage Duration	6 months
Other Criteria	N/A

VORICONAZOLE INJECTION

Products Affected

- Voriconazole INJ

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 weeks
Other Criteria	N/A

VPRIV

Products Affected

- Vpriv

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme Assay demonstrating deficiency of beta-glucocerebrosidase enzyme activity.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For long-term ERT for pediatric and adult patients with Type 1 Gaucher Disease

VYEPTI

Products Affected

- Vyepti

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Medication will not be used in combination with Botox. Medication will not be used in combination with another Calcitonin Gene-Related Peptide (CGRP) Inhibitor (injectable or oral).
Required Medical Information	Diagnosis of Migraine (chronic or episodic). If Chronic Migraine (CM): Documentation that medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Documented trial and failure, contraindication, or intolerance to at least 2 American Headache Society level A or B migraine prophylactic therapies with claims history to support member compliance with filling at least a 90 days supply within a 120 day time frame including: Beta blockers: Level A: Metoprolol, propranolol, timolol or Level B: Atenolol, nadolol, Antidepressants: Level B: Amitriptyline, venlafaxine, Anticonvulsants: Level A: Divalproex, valproic acid, topiramate.
Age Restrictions	18 years or older
Prescriber Restrictions	Neurologist, Pain Specialist, Physician who specializes in the treatment of Migraine Management
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of positive response to therapy (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

XELJANZ

Products Affected

- Xeljanz

- Xeljanz Xr

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or a potent immunosuppressant (e.g., azathioprine, cyclosporine)
Required Medical Information	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), Humira (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), Humira (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), Humira (adalimumab)). Rheumatoid Arthritis (RA): Diagnosis of active PSA or 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., Humira (adalimumab)).
Age Restrictions	JIA: 2 years or older, All others: 18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a Rheumatologist or Gastroenterologist

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Coverage Duration	12 months
Other Criteria	<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., Humira (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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)).
Age Restrictions	N/A
Prescriber Restrictions	Oncologist
Coverage Duration	MM/BMST, GCTB: 12 months. HCM: 2 months.
Other Criteria	Approve for continuation of prior therapy

XIAFLEX

Products Affected

- Xiaflex

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Dupuytren's Contracture with palpable cord: Medical chart documentation stating a contracture of a MP joint or PIP joint that is greater than or equal to 30 degrees. Peyronie's Disease: Medical chart documentation stating presence of a palpable plaque and penile curvature greater than or equal to 30 degrees before start of therapy
Age Restrictions	N/A
Prescriber Restrictions	Orthopedic or Hand Surgeon, Urologist
Coverage Duration	2 inj every 6 weeks up to 8 injections if beneficial response/penile curvature of less than 15 deg
Other Criteria	Treatment of adult patients with Dupuytren's Contracture with a palpable cord

XIFAXAN

Products Affected

- Xifaxan

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	Allergy to Rifamycin agents
Required Medical Information	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.
Age Restrictions	Travelers Diarrhea: 12 years or older. Hepatic Encephalopathy and IBS-D without constipation: 18 years or older.
Prescriber Restrictions	N/A
Coverage Duration	Travelers Diarrhea: 3 days. Hepatic Encephalopathy: 12 months. IBS-D without Constipation: 14 days.
Other Criteria	For IBS-D without constipation max 3 treatments per calendar year

XOLAIR

Products Affected

- Xolair

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	Asthma: 6 years or older. CIU: 12 years or older.
Prescriber Restrictions	Allergist, Pulmonologist, Dermatologist, Immunologist, Otolaryngologist
Coverage Duration	12 months
Other Criteria	N/A

XURIDEN

Products Affected

- Xuriden

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Orotic Aciduria
Age Restrictions	N/A
Prescriber Restrictions	Geneticist, Urologist, Nephrologist, Metabolic Specialist
Coverage Duration	12 months
Other Criteria	N/A

XYREM

Products Affected

- Sodium Oxybate
- Xyrem

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ZAVESCA

Products Affected

- Miglustat
- Yargesa

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Enzyme assay demonstrating deficiency of beta-glucocerebrosidase enzyme activity
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist, Infectious Disease Specialist, Hepatologist
Coverage Duration	Coverage duration will follow recommendation set forth by the AASLD
Other Criteria	N/A

ZEPOSIA

Products Affected

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

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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: Humira (adalimumab), Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a Gastroenterologist , or Neurologist
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of positive clinical response to therapy as evidenced by improvement from baseline

ZTALMY

Products Affected

- Ztalmy

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	2 years or older
Prescriber Restrictions	Neurologist
Coverage Duration	12 months
Other Criteria	N/A

ZURZUVAE

Products Affected

- Zurzuvae

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	PPD: Patient is 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	14 days
Other Criteria	Approve for continuation of prior therapy.

PART B VERSUS PART D

Products Affected

- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Adriamycin INJ 50MG
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Alyglo
- Aminosyn II INJ 107.6MEQ/L; 1490MG/100ML; 1527MG/100ML; 1050MG/100ML; 1107MG/100ML; 750MG/100ML; 450MG/100ML; 990MG/100ML; 1500MG/100ML; 1575MG/100ML; 258MG/100ML; 405MG/100ML; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 750MG/100ML; 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 270MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 400MG/100ML; 200MG/100ML; 500MG/100ML
- Aminosyn-pf INJ 46MEQ/L; 698MG/100ML; 1227MG/100ML; 527MG/100ML; 820MG/100ML; 385MG/100ML; 312MG/100ML; 760MG/100ML; 1200MG/100ML; 677MG/100ML; 180MG/100ML; 427MG/100ML; 812MG/100ML; 495MG/100ML; 70MG/100ML; 512MG/100ML; 180MG/100ML; 44MG/100ML; 673MG/100ML
- Aminosyn-pf 7% INJ 32.5MEQ/L; 490MG/100ML; 861MG/100ML; 370MG/100ML; 576MG/100ML; 270MG/100ML; 220MG/100ML; 534MG/100ML; 831MG/100ML; 475MG/100ML; 125MG/100ML; 300MG/100ML; 570MG/100ML; 347MG/100ML; 50MG/100ML; 360MG/100ML; 125MG/100ML; 44MG/100ML; 452MG/100ML
- Amphotericin B INJ
- Arformoterol Tartrate
- Asceniv
- Astagraf XL
- Azathioprine INJ
- Azathioprine TABS
- Baclofen INJ 20000MCG/20ML, 40MG/20ML, 500MCG/ML, 50MCG/ML
- Bivigam INJ 10%, 5GM/50ML
- Bleomycin Sulfate INJ
- Budesonide SUSP
- Cladribine
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix 8/14
- 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

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- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 8/10
- Clinimix E 8/14
- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine Modified
- Cytarabine INJ 100MG/ML, 20MG/ML
- Cytarabine Aqueous
- Dobutamine Hcl INJ 250MG/20ML
- Dobutamine Hcl/d5w INJ 5%; 1MG/ML
- Dobutamine Hydrochloride/dextrose 5%
- Dopamine Hydrochloride INJ
- Dopamine Hydrochloride/dextrose
- Dopamine/d5w INJ 5%; 3.2MG/ML
- Doxorubicin Hcl INJ 2MG/ML, 50MG
- Doxorubicin Hydrochloride INJ 10MG
- Dronabinol
- Engerix-b
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Flebogamma Dif
- Floxuridine INJ
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Gablofen
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML
- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Hepagam B INJ 312UNIT/ML
- Heplisav-b
- Hyperhep B
- Hyqvia
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol Hcl NEBU
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Lioresal Intrathecal INJ 0.05MG/ML, 10MG/20ML, 10MG/5ML
- Milrinone Lactate In Dextrose
- Morphine Sulfate INJ 10MG/ML, 4MG/ML, 5MG/ML, 8MG/ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil INJ
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nabi-hb INJ 312UNIT/ML
- Nutrilipid
- Octagam INJ 10GM/100ML, 10GM/200ML, 1GM/20ML, 2.5GM/50ML, 20GM/200ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Panzyga

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- Pentamidine Isethionate INHALATION SOLR
- Plenamine 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
- 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
- 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
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ
- Xembify

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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