Sentara® Health Plans

SENTARA COMMUNITY COMPLETE (HMO D-SNP) PRIOR AUTHORIZATION CRITERIA

(02/01/2026 – 02/28/2026)

Certain covered drugs may have additional requirements or limitations regarding coverage. We have made available documentation that outlines our criteria for Prior Authorization requirements.

PLEASE READ: This document contains information about some of the drugs we cover in this plan.

The Prior Authorization Criteria was updated on 01/20/2026

ABIRATERONE ACETATE

Products Affected

- *abiraterone oral tablet 250 mg, 500 mg*
- *abirtega*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of metastatic, castration resistant or castration-sensitive prostate cancer and meets the following (A and B): A) Requested medication will be taken with a gonadotropin-releasing hormone (GnRH) analog concurrently or member had a bilateral orchiectomy, AND B) Medication will be taken with prednisone either once daily or twice daily depending on diagnosis. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation that disease progression has not occurred required.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ACITRETIN

Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	12 months
Other Criteria	Initial: Member must have a diagnosis of psoriasis with a trial and failure or contraindication to methotrexate or cyclosporine prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ACTIMMUNE

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	Simultaneous administration of requested medication with other heterologous serum protein or immunological preparations (e.g., vaccines)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Chronic Granulomatous Disease: Prescribed by or in consultation with an immunologist, hematologist, or an infectious diseases specialist. Malignant osteopetrosis: Prescribed by or in consultation with an endocrinologist or hematologist.
Coverage Duration	12 months
Other Criteria	Chronic Granulomatous Disease (CGD)-Initial: Approve if diagnosis has been established by one of the following tests: Nitroblue tetrazolium test (negative), Dihydrorhodamine test (DHR + neutrophils less than 95 percent), a molecular genetic test identifying a gene-related mutation linked to chronic granulomatous disease or immunoblot positive for p22phox, p40phox, p47phox, p67phox, or gp91phox. Must have a trial and failure of trimethoprim/sulfamethoxazole AND itraconazole or an intolerance or contraindication to those therapies. Severe malignant osteopetrosis (SMO)-Initial: Approve if patient has diagnosis has been established by a molecular genetic test identifying a gene-related mutation linked to severe malignant osteopetrosis OR radiographic (X-ray) imaging demonstrating skeletal features related to osteopetrosis. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ACUTE HAE

Products Affected

- *icatibant*
- *sajazir*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	12 months
Other Criteria	Initial: Member has diagnosis of Hereditary Angioedema (HAE) as confirmed by either A or B: A) If member is suspected type 1 or type 2 HAE, the member has the following laboratory values (documentation with reference ranges required): low C4 complement level in mg/dL, normal C1q complement component level in mg/dL (C1q complement component level not required for members under age of 18 or members whose symptoms began before age 18), and either low C1 esterase inhibitor antigenic level in mg/dL or low C1 esterase inhibitor functional level expressed as a percent OR B) If member is suspected type 3 HAE, the member has documenation with reference ranges submitted showing the member has normal or near normal C4, C1-INH antigen, and C1-INH function AND meets either a or b: a) member has undergone genetic testing (documenation required) for further evaluation of genetic mutations in genes encoding for factor XII, plasminogen, angiopoietin-1, and kininogen OR b) member has a positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy (ie, cetirizine at 40 mg/d or the equivalent) for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema, whichever is longer. For All Types: Member must have a history of recurrent angioedema in the absence of concomitant urticaria AND there are no concomitant or recent use of medications known to cause angioedema (i.e. ACE inhibitors, ARBs). Provider attests other potential causes of

PA Criteria	Criteria Details
	angioedema have been considered and ruled out. Reauthorization: Member has previously been treated with requested medication for acute HAE attacks AND according to the prescribing physician, the patient has had a favorable clinical response with treatment. Provider attests there are no concomitant or recent use of medications known to cause angioedema (i.e. ACE inhibitors, ARBs) and other potential causes of angioedema have been considered and ruled out.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADALIMUMAB

Products Affected

- HADLIMA
- HADLIMA PUSHTOUCH
- HADLIMA(CF)
- HADLIMA(CF) PUSHTOUCH
- SIMLANDI(CF) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, targeted synthetic DMARDs, potent immunosuppressants, anti-interleukin monoclonal antibodies, or janus kinase inhibitors.
Required Medical Information	Diagnosis. For all pre-requisite drug trials, members who have already been on biologic therpies not required to step back and try a traditional systemic agent (i.e. conventional systemic DMARDs)
Age Restrictions	CD: 6 years and older. UC: 5 years and older PP: 18 years and older
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: RA/AS/JIA/JRA: Rheumatologist. PsA: Rheumatologist or dermatologist. PsO and HS: Dermatologist. UC/CD: Gastroenterologist. UV: Ophthalmologist.
Coverage Duration	12 months
Other Criteria	Rheumatoid Arthritis (RA)/Polyarticular Juvenile Idiopathic Arthritis (PJIA)/Juvenile Rheumatoid Arthritis (JRA): Initial: Approve if member has diagnosis of moderately to severely active disease and member has tried and failed one conventional synthetic DMARD for at least 3 months (i.e. methotrexate, leflunomide, sulfasalazine). Plaque Psoriasis (PsO)-Initial: Approve if the member has chronic moderate to severe disease and member has tried and failed at least one systemic therapy for 3 months with inadequate results (i.e. phototherapy, methotrexate, acitretin). Crohn's Disease (CD)-Initial: Approve if the member has moderate-to-severe disease based on evidence of large or deep ulcers, strictures, or extensive areas of disease and/or evidence of stricturing, penetrating, or perianal disease on endoscopy. Ankylosing Spondylitis (AS): Approve if the member has signs and symptoms of active disease (i.e. back pain and stiffness in the lower back and hips, neck pain and fatigue, skin rashes) and

PA Criteria	Criteria Details
	member has tried and failed an NSAID at target anti-inflammatory doses or maximally tolerated dose. Psoriatic Arthritis(PsA)/Juvenial Psoriatic Arthritis (JPsA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following (documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Hidradentis Suppurativa (HS)-Initial: Approve if the member has tried at least one other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Ulcerative Colitis (UC)-Initial: Approve if the member has moderate-to-severe disease based on the following: A) Member presents with frequent, bloody stools that occur 6 or more times daily or frequent and heavy rectal bleeding AND B) Member has severe inflammation or ulcers as visualized on endoscopy. Uveitis-Initial: Approve if the member has tried and failed one conventional synthetic DMARD for at least 3 months (i.e. methotrexate, leflunomide, sulfasalazine). For all indications, prescriber must attest to performing a latent tuberculosis (TB) test prior to starting treatment and monitoring for active TB throughout treatment even if initial latent TB test is negative. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ADBRY

Products Affected

- ADBRY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with any other monoclonal antibody that can be used to treat the same indication as the requested medication
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Must be prescribed by or in consultation with an allergist, immunologist, or dermatologist.
Coverage Duration	12 months
Other Criteria	Atopic Dermatitis (AD)-Initial: Approve if member has a diagnosis of atopic dermatitis and has tried and failed one prescription strength topical corticosteroid OR tacrolimus ointment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of pulmonary arterial hypertension (PAH) with chart notes documenting all the following are required: A) mean arterial pressure (mPAP) measured greater than or equal to 20 mmHg at rest, B) pulmonary artery wedge pressure (PAWP) measured less than or equal to 15 mmHg, AND C) pulmonary vascular resistance (PVR) greater than or equal to 2 woods units. Member must meet either A or B: A) Member has PAH WHO Group 1 confirmed by hemodynamic definitions obtained from a right heart catheterization (RHC) (documentation required) AND member has tried and failed or has a contraindication to sildenafil OR B) Member has PAH WHO Group 4, which includes Chronic Thromboembolic Pulmonary Hypertension (CTEPH) with the member meeting BOTH i and ii (documentation required): i) Diagnosis of CTEPH is confirmed by CT pulmonary angiography, pulmonary angiography, or V/Q (ventilation-perfusion) scan. Member must have tried and failed surgical treatment or member has inoperable CTEPH. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

AG EPCLUSA

Products Affected

- SOFOSBUVIR-VELPATASVIR

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Genotype (including unknown)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

AG HARVONI

Products Affected

- LEDIPASVIR-SOFOSBUVIR

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Genotype (including unknown)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

AIMOVIG

Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another injectable CGRP inhibitor
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Migraine Prevention-Initial: Approve if the member has a diagnosis of chronic migraine with or without aura based upon ICHD-3 criteria: Member has migraine-like or tension-type headaches occuring on 15 or more days/month for more than 3 months and on at least 8 days per month for greater than 3 months, fulfills any of the following A, B, or C: A) Members having migraine without aura has headaches with at least two of the four characteristics: unilateral location, pulsating quality, moderate or severe pain intensity, aggravation by or causing avoidance of routine physical activity (e.g., walking or climbin stairs) AND at least one of the following occurred during the headache: nausea and/or vomiting, photophobia and/or phonophobia, B) Members having migraine with aura has headaches with one or more of the following fully reversible aura symptoms: visual, sensory, speech and/or language, motor brainstem, retinal AND at least three of the following six characteristics: at least one aura symptom spreads gradually over greater than or equal to 5 minutes, two or more aura symptoms occur in succession, each individual aura symptom lasts 5-60 minutes, at least one aura symptom is unilateral, at least one aura symptom is positive, the aura is accompanied, or followed within 60 minutes by headache, or C) believed by the member to be migraine at onset and relieved by a triptan or ergot derivative. Provider attests the diagnosis is not better accounted for by another ICHD-3 diagnosis (i.e. medication overuse) and medication will not be used

PA Criteria	Criteria Details
	concomitantly with onabotulinumtoxin A (Botox). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AKEEGA

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Prostate cancer-Initial: Approve if the member meets the following (A, B, C, and D): A) Patient has metastatic castration-resistant prostate cancer, AND B) Member has deleterious or suspected deleterious BRCA-mutated (BRCAm) disease as determined by an FDA-approved test, AND C) The medication is used in combination with prednisone, AND D) Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. Member has had a bilateral orchiectomy Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has anaplastic lymphona kinase (ALK) positive disease as detected by an FDA approved test and meets either A or B: A) Member has metastatic disease OR B) Member will be using medication as adjuvant treatment following tumor resection (tumors greater than or equal to 4 cm or node positive). Provider must attest to monitoring liver laboratory tests every two weeks during the first three months of treatment, then once a month and as clinically indication, with more frequent testing in members who develop transaminase and bilirubin elevations. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALOSETRON

Products Affected

- *alosetron*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of chronic irritable bowel syndrome (IBS). Member must have a trial and failure or contraindication to two medications uded to treat IBS-D prior to approval (i.e. loperamide, antispasmodics). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	IgA deficient members or presence of antibodies against IgA
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Alpha1-Antitrypsin (AAT) Deficiency-Initial: Member must have a diagnosis of congenital AAT deficiency with submitted clinical evidence of emphysema (i.e. FEV1 value between 30 and 65%). Member must have one of the following phenotype deficiencies (documentation required): Pi*ZZ, Pi*Z (null), or Pi* (null)(null) protein phenotypes (homozygous). Member must have a pre-treatment serum AAT less than 11 micromol/L (less than 80 milligrams per deciliter by radial immunodiffusion or less than 57 milligrams per deciliter by nephelometry). Provider attests member will continue conventional therapy for emphysema (e.g. bronchodilators) Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and member has continued conventional therapy for emphysema (e.g. bronchodilators).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ALUNBRIG

Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease that is anaplastic lymphona kinase (ALK) positive as detected by an FDA approved test. Member must have a trial and failure of alectinib (Alecensa) prior to approval or a medical reason as to why it cannot be started or continued. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AMBRISENTAN

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, idiopathic pulmonary fibrosis (IPF)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	12 months
Other Criteria	Intial: Member must have a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1. PAH must be confirmed by right heart catherterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than 20 mmHg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than or equal to 3 wood units. Must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ANTIDEPRESSANTS

Products Affected

- AUVELITY
- FETZIMA ORAL CAPSULE,EXT REL 24HR DOSE PACK 20 MG (2)- 40 MG (26)
- FETZIMA ORAL CAPSULE,EXTENDED RELEASE 24 HR
- TRINTELLIX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has had prior therapy, contraindication, or intolerance in adequate doses (i.e. as determined by the treating provider based on individual patient characteristics) and duration (i.e. at least 8 weeks for each antidepressant) with either A or B: A) two preferred SSRIs or B) one preferred SSRI AND venlafaxine ER. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ANTIFUNGALS (IV)

Products Affected

- *fluconazole in nacl (iso-osm) intravenous piggyback 200 mg/100 ml, 400 mg/200 ml*
- *voriconazole intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

APTIOM

Products Affected

- *eslicarbazepine oral tablet 200 mg, 400 mg, 600 mg, 800 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of partial-onset seizures (i.e. focal seizures). Member must have tried and failed or have a contraindication to two or more generic formulary antiepileptic medications used to treat the same indication: levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin, or topiramate. Provider must attest the member will not be taking the medication concomitantly with oxcarbazepine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with biologics
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	CAPS: Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA: Prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis: Prescribed by or on consultation with a cardiologist or rheumologist.
Coverage Duration	12 months
Other Criteria	Cryopyrin-Associated Periodic Syndromes (CAPS)-Initial-Approve if the member is at least 12 years of age and has a confirmed diagnosis of CAPS, including Familial Cold Autoinflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS). Deficiency of Interleukin-1 Receptor Antagonist (DIRA)-Initial: Approve if the member weighs at least 10 kg AND a genetic test confirms a mutation in the IL1RN gene. Must have a trial and failure of anakinra (Kineret) prior to approval. Pericarditis-Initial: Approve if the member is at least 12 years of age and has a diagnosis of recurrent pericarditis (defined as two recurrent episodes that occur a minimum of 4 to 6 weeks apart) and symptoms consist of one of the following: pericarditis chest pain, pericardial rub, pericardial effusion, or ST-segment elevation or PR depression. Member must have a trial and failure or contraindication to colchicine. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections
Coverage Duration	12 months
Other Criteria	Mycobacterium Avium Complex (MAC)-Initial-Approve if the member has a positive sputum culture for mycobacterium avium complex for which the member has limited or no alternative treatment options. Member must have failed to achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g. macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin)). Member's culture must have been collected after the 6 month multidrug therapy completion. The Mycobacterium avium complex isolate must be susceptible to the requested medication with a minimum inhibitor concentration (MIC) of less than or equal to 64 microgram/mL AND medication will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). Reauthorization: Approve if the requested medication will be used in conjunction with a background multidrug regimen AND i. Member meets ONE of the following criteria (A or B): A)Member has not achieved negative sputum cultures for Mycobacterium avium complex OR B) Member has not achieved 3 consecutive negative monthly sputum cultures by month 6.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ARMODAFINIL

Products Affected

- *armodafinil*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	12 months
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD)-Initial: Approve if the member is working a shift work schedule (i.e., unconventional work hours) and has symptoms of insomnia during the major sleep period and excessive sleepiness (including inadvertent sleep) during the major awake period. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-Approve. Excessive daytime sleepiness associated with Narcolepsy-Initial: Approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ATYPICAL ANTIPSYCHOTICS

Products Affected

- CAPLYTA
- FANAPT
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B
- FANAPT TITRATION PACK C
- LYBALVI
- REXULTI ORAL TABLET
- SECUADO
- VRAYLAR ORAL CAPSULE 0.5 MG, 0.75 MG, 1.5 MG, 3 MG, 4.5 MG, 6 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Agitation Associated with Dementia Due to Alzheimers Disease-Initial: Approve brexpiprazole (Rexulti) if the member has clinically diagnosed agitation associated with dementia due to Alzeheimers Disease and requested medication will not be used on an as needed treatment for agitation. All Other Indications-Initial: Approve if member has had a trial and failure or contraindication to at least two generic formulary atypical antipsychotic agents. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AUGTYRO

Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has locally advanced or metastatic disease. Member must have ROS1-positive arrangement mutation as detected by an approved test. Solid Tumors-Initial: Approve if the member has solid tumors meeting all the following A, B, C: A) Tumor has a neurotropic tyrosine receptor kinase (NTRK) gene fusion as detected by an FDA-approved test, B) Tumors are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and C) Tumors have progressed following treatment or have no satisfactory alternative therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

AUSTEDO

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR
- AUSTEDO XR TITRATION KT(WK1-4) ORAL TABLET, EXT REL 24HR DOSE PACK 12-18-24-30 MG

PA Criteria	Criteria Details
Exclusion Criteria	Suicidal, or untreated/inadequately treated depression in members with Huntington's disease, hepatic impairment, concomitant use with reserpine, MAOIs, tetrabenazine, or valbenazine
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Tardive Dyskinesia (TD) - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea associated with Huntington's disease - Prescribed by or after consultation with a neurologist.
Coverage Duration	12 months
Other Criteria	Tardive Dyskinesia (TD)-Initial: Member has prior or current use of dopamine receptor blocking drug (e.g. chlorpromazine, olanzapine, metoclopramide). Member is experiencing involuntary movements and provider attests other causes of involuntary movements have been ruled out. Member must have chart note documentation of one of the following: a) patient has persistent symptoms of TD despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. TD-Reauthorization: Documentation of positive clinical response to therapy. Documentation showing member remains a candidate for treatment based upon prescriber's assessment AND evaluation to taper dose of or to discontinue therapy or clinical rationale for why this would not be appropriate. Chorea associated with Huntington's Disease (HD)-Initial: Approve if the diagnosis of Huntington's Disease is confirmed by one of the following: 1) HD mutation analysis indicating expanded CAG repeat greater than or equal to 36 in the Huntington gene (HTT) (documentation required) genetic testing or 2) Member has a positive family history of HD with autosomal dominant inheritance pattern.

PA Criteria	Criteria Details
	Member exhibits one or more symptoms of HD (i.e. finger tapping, rigidity, dysarthria, dysphagia, depression, or cognitive) (documentation required). Provider attests the member will be monitored for psychiatric side effects of medication. HD-Reauthorization: Provider attestation to continual monitoring of psychiatric side effects AND attestation the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AVMAPKI-FAKZYNJA

Products Affected

- AVMAPKI-FAKZYNJA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of low-grade serous ovarian cancer (LGSOC) that is KRAS-mutated as determined by an FDA-approved test. Disease must be recurrent after prior systemic therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AVONEX

Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agent used for multiple sclerosis
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of relapsing forms of multiple sclerosis (RRMS). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AYVAKIT

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	GIST-Initial: Member must have a confirmed diagnosis of gastrointestinal stromal tumor (GIST) that harbors a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations as detected by an FDA-approved test. Member must have tried and failed two or more of the following prior to request: imatinib, sunitinib, dasatinib, regorafenib, or ripretinib. Systemic Mastocytosis-Initial: Member must have a platelet count greater than or equal to 50,000/mcL. Member has confirmed diagnosis of indolent systemic mastocytosis (ISM) or one of the following subtypes of advanced systemic mastocytosis (AdvSM): aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). All Indications-Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

BALVERSA

Products Affected

- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Urothelial Carcinoma-Initial: Approve if the member meets A, B, and C: A) Member must have locally advanced or metastatic disease, B) Member has susceptible fibroblast growth factor receptor 3 (FGFR3) genetic alterations, and C) Member's disease has progressed on or after at least one line of prior systemic therapy including a Programmed Cell Death Protein 1 (PD-1) or Programmed Death-Ligand 1 (PD-L1) inhibitor (i.e. avelumab, pembrolizumab), if eligible. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BENLYSTA

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Severe active central nervous system lupus or concomitant therapy with biologic therapies
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist. Lupus Nephritis-Prescribed by or in consultation with a nephrologist or rheumologist.
Coverage Duration	Initial: 6 months, Reauthorization: 12 months
Other Criteria	Systemic Lupus Erythematosus (SLE)-Initial: Approve if the patient has autoantibody-positive SLE with documentation of one of the following: 1) Positive antinuclear antibodies (ANA) titre greater than or equal to 1:80 and/or anti-double-stranded DNA antibody [anti-dsDNA] above the upper limit of normal (based on reference range provided by the laboratory). Must have a trial and failure or contraindication of hydroxychloroquine, azathioprine, methotrexate, or mycophenolate. Must be on concomitant therapy with one of the following: non-steroidal anti-inflammatory drugs (NSAIDs), antimalarials, corticosteroids, or immunosuppressants. SLE-Reauthorization: Documentation from prescriber indicating improvement in condition and continual use of standard therapy (i.e. corticosteroids, antimalarials, NSAIDs, or immunosuppressants). Lupus Nephritis (LN)-Initial: Must have active lupus nephritis confirmed by a kidney biopsy (documenation required). Baseline renal function showing proteinuria must be submitted. Member must be on concomitant standard immunosuppressive therapy (defined as induction therapy with systemic corticosteroids and mycophenolate or cyclophosphamide followed by maintenance therapy with mycophenolate mofetil or azathioprine)). Must not be used in combination with voclosporin (Lupkynis). LN-Reauthorization: Member continues to receive immunosuppressive therapy with mycophenolate mofetil or azathioprine. Provider submits renal

PA Criteria	Criteria Details
	function tests showing improvement from baseline (e.g. decreased proteinuria, improvement in urine creatinine ratio, improved eGFR, etc).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BESREMI

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation or suicide attempt, hepatic impairment (Child-Pugh B or C), history or presence of active serious or untreated autoimmune disease, immunosuppressed transplant recipients
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Polycythemia Vera (PV)-Initial: Member must have confirmed diagnosis based on one the following: 1) Hemoglobin greater than 16.5 g/dL for men or 16.0 g/dL for women, 2) Hematocrit greater than 49% for men or 48% for women, 3) Increased red cell mass based on reference range provided by the laboratory. Member must have a trial and failure or contraindication to hydroxyurea prior to approval.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BETASERON

Products Affected

- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of relapsing forms of multiple sclerosis (RRMS). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

BEXAROTENE (ORAL)

Products Affected

- *bexarotene oral*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Cutaneous T-Cell Lymphoma (CTCL)-Initial: Approve if the member has diagnosis AND is refractory to at least one prior systemic therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BEXAROTENE (TOPICAL)

Products Affected

- *bexarotene topical*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, hematologist, or dermatologist
Coverage Duration	12 months
Other Criteria	Cutaneous T-Cell Lymphoma (CTCL)-Initial: Approve if the member has diagnosis (Stage IA and IB) AND disease is refractory or persistent after other therapies or who have not tolerated other therapies. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BOSENTAN

Products Affected

- *bosentan oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	12 months
Other Criteria	Intial: Member must have a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1. PAH must be confirmed by right heart catherterization. Must have chart documentation of right heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than 20 mmHhg, pulmonary capillary wedge pressure OR left atrial pressure OR left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than or equal to 3 wood units. Must have WHO Functional Class II-IV symptoms. Must have baseline liver function tests (AST, ALT), prior to initiation of therapy. Must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

BOSULIF

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Myelogenous Leukemia (CML)-Initial: Approve if the member meets A or B: A) Member is an adult with accelerated, or blast phase philadelphia chromosome positive (Ph+) CML AND had resistance or intolerance to prior therapy or B) Member has chronic phase CML, newly-diagnosed or resistant or intolerant to prior therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BOTOX

Products Affected

- BOTOX

PA Criteria	Criteria Details
Exclusion Criteria	Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, rejuvenation of the peri-orbital region)
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Migraine headache prevention-prescribed by, or after consultation with, a neurologist or HA specialist.
Coverage Duration	Authorization will be for 12 months
Other Criteria	Blepharospasm Associated with Dystonia or Strabismus-approve, Cervical Dystonia-approve, Hyperhidrosis, primary axillary-approve, Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program. Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate), Migraine Headache Prevention-must have 15 or more migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy) AND have tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class (e.g., beta-blocker, anticonvulsant, tricyclic antidepressant) and patient has had inadequate efficacy or adverse events. If the patient is currently taking Botox for migraine headache prevention, patient must have had significant clinical benefit. Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency-approve if the patient has tried at least one other pharmacologic therapy. Spasticity, limb-approve. Urinary incontinence associated with a neurological condition-approve if the patient has tried at least one other pharmacologic therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Achalasia, Anal Fissure, Chronic facial pain/pain associated with TMJ dysfunction, Chronic low back pain, Dystonia, other than cervical, Essential tremor, Hyperhidrosis, gustatory, hyperhidrosis, Palmar/Plantar and facial, Myofascial pain, Ophthalmic disorders, other than blepharospasm or Strabismus, Sialorrhea, chronic, Spasticity, other than limb (i.e., due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm)
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRAFTOVI

Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
Exclusion Criteria	Members with wild-type BRAF melanoma, wild-type BRAF CRC, or wild-type BRAF NSCLC
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma-Initial: Approve if the member has unresectable, advanced or metastatic melanoma with a BRAF V600E or V600K mutation as detected by an FDA-approved test. Medication must be used in combination with binimetinib (Mektovi). Colorectal Cancer (CRC)-Initial: Approve if the member has metastatic disease with BRAF V600E mutation as detected by an FDA-approved test and meets one of the following criteria A or B: A) The requested medication will be used in combination with cetuximab and mFOLFOX6 or B) Member has history of prior therapy for mCRC AND requested medication will be used in combination with cetuximab. NSCLC-Initial: Approve if member has metastatic disease with a BRAF V600E mutation as detected by an FDA-approved test AND medication will be taken in combination with binimetinib (Mektovi). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

BRIVIACT

Products Affected

- BRIVIACT ORAL SOLUTION
- BRIVIACT ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial-Approve if member has a diagnosis of partial-onset seizures. Member must have a trial and failure or contraindication to two generic formulary antiepileptic drugs (i.e. levetiracetam, topiramate, lamotrigine). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BRUKINSA

Products Affected

- BRUKINSA ORAL CAPSULE
- BRUKINSA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Mantle Cell Lymphoma (MCL)-Initial: Approve if the member has tried at least one other therapy prior to requested medication. Marginal Zone Lymphoma-Initial: Approve if the member has relapsed or refractory disease after a trial and failure of at least one anti-CD20 based regimen prior to the requested medication. Chronic Lymphocytic Leukemia (CLL)/Small lymphocyctic lymphoma (SLL) or Waldenstrom Macroglobulinemia (WM)- Initial: Approve. Chronic Lymphocytic Leukemia (CLL)/Small lymphocyctic lymphoma (SLL)-Approve. Follicular Lymphoma (FL)-Initial: Approve if member has refractory or relapsed disease after a trial and failure of at least two or more systemic regimens prior to requested medication AND member will be using in combination with obinutuzumab (Gazyva).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BUDESONIDE EC (UCERIS)

Products Affected

- *budesonide oral tablet,delayed and ext.release*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	2 months
Other Criteria	Initial: Approve if member has a diagnosis of mild to moderate active ulcerative colitis and medication will be used to induce remission of active disease. Member must have had previous treatment or intolerance to at least two of the following: sulfasalazine, balsalazide capsules, mesalamine enema or mesalamine 0.375g extended-release prior to approval. Reauthorization: Must have documentation of concurrent maintenance treatment of ulcerative colitis and and either clinical rationale from prescriber for continuation of treatment beyond 8 weeks or documentation that member is experiencing a subsequent flare-up and experienced improvement in the condition as a result of treatment with budesonide during a previous flare-up.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

C1 ESTERASE INHIBITORS

Products Affected

- HAEGARDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	12 months
Other Criteria	Initial: Member has diagnosis of Hereditary Angioedema (HAE) as confirmed by the following laboratory values (documentation with reference ranges required) in either A, B, or C: A) If member is suspected type 1 HAE, the member has: low C4 complement level in mg/dL, normal C1q complement component level in mg/ dL (C1q complement component level is not required for members under 18 years of age or if symptoms began before 18 years of age), and either low C1 esterase inhibitor antigenic level in mg/dL or low C1 esterase inhibitor functional level expressed as a percent OR B) If member is suspected type 2 HAE, the member has: low C4 complement level in mg/dL, normal C1q complement component level in mg/dL (C1q complement component level is not required for members under 18 years of age or if symptoms began before 18 years of age), and low C1 esterase inibitor functional level expressed as a percent, OR C) If member is suspected type 3 HAE, the member has: normal or near normal C4, C1-INH antigen, and C1-INH function AND meets either i or ii: i) member has undergone genetic testing (documenation required) for further evaluation of genetic mutations in genes encoding for factor XII, plasminogen, angiopoietin-1, and kininogen OR ii) member has a positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy (ie, cetirizine at 40 mg/d or the equivalent) for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema, whichever is longer. For All Types:

PA Criteria	Criteria Details
	Chart note documentation showing history of previous HAE attacks to demonstrate member is a candidate for prophylactic therapy is required. Medication must be used as prophylactic therapy for prevention of HAE attacks. Must not be on concurrent therapy with another prophylactic drug for HAE. Reauthorization: Member must not be on concurrent therapy with another prophylactic drug for HAE. Documentation submitted indicating improvement in condition required.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	DTC-12 years and older, All other indications-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Renal Cell Carcinoma (RCC)-Initial: Approve if the member has advanced disease and either A or B: A) The member will be using the requested medication as monotherapy OR B) The member will be using the requested medication as a first-line therapy in combination with nivolumab (Opdivo). Hepatocellular Carcinoma (HCC)-Initial: Approve if the member has been previously treated with sorafenib (Nexavar) and medication will be used as monotherapy. Differentiated Thyroid Cancer (DTC)-Initial: Approve if the member will be using medication as monotherapy and meets all the following (A, B, C, and D): A) Member is at least 12 years of age or older, B) Member has locally advanced or metastatic disease, C) Member is ineligible or refractory to radioactive iodine therapy, AND D) Member has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. Pancreatic Neuroendocrine Tumors (pNET)-Initial: Approve if the member is at least 12 years of age with a previously treated, unresectable, locally advanced or metastatic disease and meets either A or B: A) Member has well-differentiated pNET OR B) Member has well-differentiated extra-pancreatic neuroendocrine tumors (epNET). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CALQUENCE

Products Affected

- CALQUENCE (ACALABRUTINIB MAL)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Mantle Cell Lymphoma (MCL)-Initial: Approve if the member meets either A or B: A) Member has tried at least one prior therapy and will be using the requested medication as monotherapy OR B) Member is ineligible for autologous hematopoietic stem cell transplant (HSCT) and has previously untreated disease. Medication will be used in combination with bendamustine (Bendeka) and rituximab. Small lymphoplasmacytic lymphoma (SLL)-Initial: Approve. Chronic lymphocytic leukemia (CLL)-Initial: Approve. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CAPRELSA

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Medullary Thyroid Cancer (MTC)-Initial: Approve if the member has symptomatic or progressive locally advanced or metastatic medllary thyroid cancer that is unresectable. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CARGLUMIC ACID

Products Affected

- *carglumic acid*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a provider who specializes in the treatment of inherited metabolic disorders
Coverage Duration	NAGs, NAG, or CPS 1-Initial: 90 days, Reauth: 12 months, PA or MA: 7 days
Other Criteria	N-Acetylglutamate Synthase (NAGs)-Initial: Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia (PA) or Methylmalonic Acidemia (MA) with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater then or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist, infectious disease specialist, or a physician who specializes in the treatment of cystic fibrosis.
Coverage Duration	12 months
Other Criteria	Approve if the member has a positive culture for Pseudomonas aeruginosa in the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture). Member must be at least 7 years of age or older. Member must have FEV1 greater than or equal to 25% OR less than or equal to 75% predicted. Provider attests member is not colonized iwth Burkholderia cepacia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CENOBAMATE

Products Affected

- XCOPRI MAINTENANCE PACK
- XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 25 MG, 50 MG
- XCOPRI TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	Familial Short QT Syndrome
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial-Approve if member has a diagnosis of partial-onset seizures. Member must have a trial and failure or contraindication to two generic formulary antiepileptic drugs (i.e. levetiracetam, topiramate, lamotrigine). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CLOBAZAM

Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*
- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Lennox-Gastaut Syndrome (LGS)-Initial: Approve if member has tried one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. Treatment refractory seizures/epilepsy-Initial: Approved if the member has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COBENFY

Products Affected

- COBENFY
- COBENFY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Urinary or gastric retention, untreated narrow-angle glaucoma, moderate or severe hepatic impairment
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of schizophrenia and chart note documentation showing two or more of the following symptoms: 1) delusions 2) hallucinations 3) disorganized speech 4) grossly disorganized or catatonic behavior 5) negative symptoms (i.e reduced emotion expression, lack of motivation, social withdrawal). Member must have an inadequate response or significant side effect/toxicity or have a contraindication to cariprazine (Vraylar) AND brexipiprazole (Rexulti). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COMETRIQ

Products Affected

- COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	MTC-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of progressive metastatic medllary thyroid cancer. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic lymphocytic leukemia (CLL)/Small lymphocytic leukemia (SLL)-Initial: Member must have a confirmed diagnosis of CLL or SLL. Member must have tried and failed ibrutinib (Imbruvica) and one more prior line of systemic therapy for the same indication prior to request. CLL/SLL-Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CORLANOR

Products Affected

- CORLANOR ORAL SOLUTION
- *ivabradine*

PA Criteria	Criteria Details
Exclusion Criteria	Blood pressure less than 90/50 mmHg, current acute decompensated heart failure, sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present. Severe hepatic impairment. Dependence on a pacemaker, where heart rate is maintained exclusively by the pacemaker, such as ventricular or atrioventricular pacing more than 40% of the day or demand pacemakers set to a rate greater than 60 beats per minue. Use in combination with a strong CYP3A4 inhibitor (e.g. itraconazole, clarithromycin, etc).
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	12 months
Other Criteria	Chronic Heart Failure (CHF)-Initial: Must be an adult member with a diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Member has a left ventricular ejection fraction less than or equal to 35% AND is in sinus rhythm. Member has a resting heart rate of greater than or equal to 70 beats per minute. Member meets one of the following A or B: A) Member is on a beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate extended release) at a maximally tolerated dose, or B) Member has a contraindication or intolerance to beta-blocker therapy. Member should have a trial and failure, contraindication, or intolerance to maximally tolerated doses of an ACE inhibitor (e.g., captopril, enalapril, lisinopril) or ARB (e.g., candesartan, losartan, valsartan). Dilated Cardiomyopathy (DCM)-Initial: Diagnosis of heart failure due to DCM and member has NYHA Class II, III, or, IV symptoms. Member is in sinus rhythm and has an elevated heart rate. Member has a trial and failure, contraindication or intolerance to one of the following A, B, or C: A) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), B)

PA Criteria	Criteria Details
	Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or C) Diuretic Agent (e.g., spironolactone, furosemide). All Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COSENTYX

Products Affected

- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)
- COSENTYX SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML
- COSENTYX UNOREADY PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, targeted synthetic DMARDs, potent immunosuppressants, anti-interleukin monoclonal antibodies, or janus kinase inhibitors.
Required Medical Information	Diagnosis, For all pre-requisite drug trials, members who have already been on biologic therpies not required to step back and try a traditional systemic agent (i.e. conventional systemic DMARDs).
Age Restrictions	HS: 18 years and older
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: PsO and HS: Dermatologist. PsA: Rheumatologist or dermatologist. AS, nr-axSpA, ERA: Rheumatologist.
Coverage Duration	12 months
Other Criteria	Ankylosing Spondylitis (AS)-Initial: Approve if the member has signs and symptoms of active disease (i.e. back pain and stiffness in the lower back and hips, neck pain and fatigue, skin rashes) and member has tried and failed or have a contraindication to an NSAID at target anti-inflammatory doses or maximally tolerated dose. Non-radiographic Axial Spondyloarthritis (nr-axSpA)-Initial: Approve if the member has at least one documented magnetic resonance imaging (MRI) scan with results showing inflammation OR C-reactive protein (CRP) levels above the upper limit of normal. Member must have tried and failed or have a contraindication to an NSAID at target anti-inflammatory doses or maximally tolerated dose. Psoriatic Arthritis (PsA)/Enthesitis Related Arthritis (ERA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following (documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). For ERA only, member must have tried and failed or have a contraindication to an NSAID at target anti-inflammatory doses or maximally tolerated dose. Plaque Psoriasis (PsO)-

PA Criteria	Criteria Details
	Initial: Approve if the member has chronic moderate to severe disease and member has tried and failed or has a contraindication to at least one systemic therapy for 3 months with inadequate results (i.e. phototherapy, methotrexate, acitretin). Hidradenitis Suppurativa (HS)-Initial: Approve if the member has moderate to severe disease defined as Hurley Stage II (i.e. one or more widely separated recurrent abscesses with tract information and scars) or Hurley Stage III (i.e. multiple interconnected tracts and abscesses throughout an entire area). Member must have tried and failed or have a contraindication to at least one other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma-Initial: Approve if the member has unresectable or metastatic melanoma with a BRAF V600E or V600K mutation as detected by an FDA-approved test. Medication must be used in combination with vemurafenib (Zelboraf). Histiocytic neoplasms-Initial: Approve if the member has diagnosis and will be using the requested medication as monotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRESEMBA (ORAL)

Products Affected

- CRESEMBA ORAL CAPSULE 186 MG, 74.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Co-administration of strong CYP3A4 inducers (i.e. rifampin, carbamazepine, St. John's Wort, long-acting barbiturates) and strong CYP3A4 inhibitors (i.e. ketoconazole or high-dose ritonavir [400mg every 12 hours]). Members with familial short QT syndrome.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	Mucormycosis-Initial: Approve if the member has a diagnosis of mucormycosis (laboratory and clinical documentation confirming organism must be submitted). Member must have a trial and failure, intolerance, or contraindication to liposomal amphotericin B AND posaconazole prior to approval. Invasive Aspergillosis-Initial: Approve if the member has a diagnosis of invasive aspergillosis (laboratory and clinical documentation confirming organism must be submitted). Member must have a trial and failure, intolerance, or contraindication to voriconazole prior to approval. Reauthorization: Approve if the member requires secondary prophylaxis to prevent disease recurrence of invasive aspergillosis or mucormycosis and provider attests liver function tests are being monitored, and the member is NOT experiencing clinical signs and symptoms of liver disease or hepatic failure.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	Yes

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

CRYSVITA

Products Affected

- CRYSVITA

PA Criteria	Criteria Details
Exclusion Criteria	Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease
Required Medical Information	Diagnosis, lab values
Age Restrictions	TIO-2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or nephrologist (initial therapy)
Coverage Duration	XLH-1 year (initial/cont), TIO-initial-6 months, cont-1 year
Other Criteria	XLH-Initial therapy-Approve if the patient has had a baseline (prior to any XLH treatment) serum phosphorus level that was below the normal range for age and patient meets ONE of the following (a or b): a) The patient has had a baseline (i.e., prior to any XLH treatment tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender OR b) The patient has had a genetic test confirming the diagnosis of X-linked hypophosphatemia via identification of a PHEX mutation AND if the patient is greater than or equal to 18 years of age, the patient is currently exhibiting one or more signs or symptoms of XLH. Continuation-approve if the patient is continuing to derive benefit as determined by the prescribing physician. TIO-approve if the patient has a mesenchymal tumor that cannot be curatively resected or identified/localized AND the patient is currently exhibiting one or more signs or symptoms of TIO AND patient has had a baseline (prior to any TIO treatment) serum phosphorus level that was below the normal range for age AND patient has had a baseline (prior to any TIO treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender. Cont-approve if the patient is continuing to derive benefit as determined by the prescribing physician.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTEAMINE (OPHTHALMIC)

Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
Coverage Duration	12 months
Other Criteria	Approve if the member has corneal cysteine crystal deposits confirmed by slit-lamp examination.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTEAMINE (ORAL)

Products Affected

- CYSTAGON

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Procysbi
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	12 months
Other Criteria	Nephropathic Cystinosis-Initial: Approve if the member has a diagnosis confirmed by any of the following: 1) White blood cell cystine concentration is greater than 1 nmol per half-cystine per mg of protein using the normal reference range for the reporting laboratory, 2) Genetic testing confirmed a mutation of the CTNS gene, or 3) Elevated baseline granulocyte cystein levels greater than 1 nmol per half-cysting per mg of protein using the normal reference range for the reporting laboratory. Reauthorization: Must have documentation from prescriber indicating improvement in condition and a reduction in WBC cystine levels since beginning treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DALFAMPRIDINE

Products Affected

- *dalfampridine*

PA Criteria	Criteria Details
Exclusion Criteria	Moderate to severe renal impairment (CrCl less than or equal to 50 mL/min), history of seizure, concomitant use with other forms of 4-aminopyridine
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consulatation with a neurologist or multiple sclerosis specialist
Coverage Duration	12 months
Other Criteria	Initial-Approve if the member is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with multiple sclerois, and the member has impaired ambulation as evaluated by an objective measure (e.g., timed 25 foot walk and multiple sclerosis walking scale-12). Reauthorization-Approve if the member continues to meet all the initial criteria and has responded to or is benefiting from therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DANZITEN

Products Affected

- DANZITEN

PA Criteria	Criteria Details
Exclusion Criteria	Members with hypokalemia, hypomagnesemia, or long QT syndrome. Concomitant use of medications known to prolong the QT interval.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Myeloid Leukemia (CML)-Initial: Approve if the member has Philadelphia chromosome positive (Ph+) disease as detected by an FDA-approved test and meets one of the following A, B, or C: A) Member has newly diagnosed disease in the chronic phase OR B) Member has chronic phase and accelerated phase Ph+ CML that is resistant to or intolerant to prior therapy that included imatinib. Provider must attest that prior to administration member will be monitored for hypokalemia or hypomagnesemia and deficiencies will be corrected. ECGs to monitor the QTc at baseline, seven days after initiation, and periodically thereafter, and following any dose adjustments. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

DASATINIB

Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Members with T315I, F317L/V/I/C, or V299L mutations as detected by an FDA-approved test
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Myeloid Leukemia-Initial: Approve if the member has Philadelphia chromosome-positive (Ph+) CML as determined by an FDA-approved test and meets either A, B, C, or D: A) Member is a an adult with newly diagnosed disease in the chronic phase, B) Pediatric member one year of age or older in the chronic phase, C) Pediatric member one year of age or older with newly diagnosed disease where the requested medication will be used in combination with chemotherapy, OR D) Member is an adult with chronic, accelerated, or myeloid or lymphoid blast phase disease that has resistance or intolerance to prior therapy including imatinib. Acute Lymphoblastic Leukemia (ALL)-Initial: Approve if the member has Ph+ disease as determined by an FDA-approved test that has resistance or intolerance to prior therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

DAURISMO

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member meets all the criteria A, B, C: A) Medication will be used in combination with cytarabine, B) the member is 75 years of age or older OR has comorbidiities that preclude intensive chemotherapy, and C) medication will be used as a treatment for induction therapy, post-induction/consolidation therapy, or relapsed or refractory disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEFERASIROX

Products Affected

- *deferasirox oral tablet*
- *deferasirox oral tablet, dispersible*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant advanced malignancy or high-risk myelodyspastic syndrome. Serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance less than 40 mL/min
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	12 months
Other Criteria	Transfusion-related Iron Overload-Initial: Approve if the member member has a diagnosis of chronic iron overload from receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) and prior to starting therapy has a serum ferritin level greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia (NTDT) syndromes chronic iron overload-Initial: Approve if member has chronic iron overload NTDT and prior to starting therapy the member has a serum ferritin level is greater than 300 mcg/L. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIABETIC SUPPLIES

Products Affected

- *alcohol pads*
- GAUZE PADS 2 X 2
- INSULIN PEN NEEDLE
- INSULIN SYRINGE (DISP) U-100 0.3 ML 29 GAUGE, 1 ML 29 GAUGE X 1/2", 1/2 ML 28 GAUGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIACOMIT

Products Affected

- DIACOMIT ORAL CAPSULE 250 MG, 500 MG
- DIACOMIT ORAL POWDER IN PACKET 250 MG, 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an neurologist
Coverage Duration	12 months
Other Criteria	Dravet Syndrome-Initial: Approve if the member weighs 7 kg (15.4 lbs) or more and is concomitantly receiving clobazam. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DICLOFENAC SODIUM (DROPS)

Products Affected

- *diclofenac sodium topical drops*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	2 months
Other Criteria	Initial: Approve if the member has a diagnosis of osteoarthritis of the knee(s). Member must have a trial and failure or contraindication to at least two of the following: diclofenac sodium, meloxicam tablets, naproxen. Provider must attest the lowest effective dose and shortest duration of treatment will be utilized. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DICLOFENAC SODIUM (TOPICAL)

Products Affected

- *diclofenac sodium topical gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	Coronary Artery Bypass Graft (CABG) surgery
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 months
Other Criteria	Initial: Approve if the member has a diagnosis of actinic keratosis. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and the member requires further treatment up to a maximum of 90 consecutive days.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIFICID

Products Affected

- DIFICID ORAL SUSPENSION FOR RECONSTITUTION
- *fidaxomicin*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	10 Days
Other Criteria	Approve if member has a diagnosis of Clostridium difficile based on a positive stool test. Reauthorization: Approve if member has a positive stool test within 8 weeks after completion of therapy for a prior CDI episode, for which symptoms and signs resolved.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIMETHYL FUMARATE

Products Affected

- *dimethyl fumarate oral capsule,delayed release(dr/ec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has relapsing form of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DRIZALMA

Products Affected

- DRIZALMA SPRINKLE ORAL
  CAPSULE, DELAYED REL SPRINKLE
  20 MG, 30 MG, 40 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. Must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact capsule.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Fibromyalgia-Initial: Member must have a trial of gabapentin solution with inadequate response or significant side effects/toxicity or have a contraindication to this therapy. GAD-Initial: Member must have a trial of sertraline concentrate with inadequate response or significant side effects/toxicity or have a contraindication to this therapy. MDD-Initial: Member must have a trial of fluoxetine solution with inadequate response or significant side effects/toxicity or have a contraindication to this therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DROXIDOPA

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a neurologist
Coverage Duration	12 months
Other Criteria	Neurogenic Orthostatic Hypotension (NOH)-Initial: Approve if the member meets ALL of the following criteria: a) Member has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, B) Member has a persistent, consistent decrease in systolic blood pressure of at least 20 mmHg or a decrease in diastolic blood pressure of at least 10 mmHG within 3 minutes of standing or head-up tilt test, and C) Member has tried and failed or has a contraindication to midodrine. Chart note documentation showing how the diagnosis was made is required. Member must have chart note documentation indicating an attempt to discontinue or dose decrease drugs which can cause orthostatic hypotension (i.e. nitrates, antiparkinsonian agenents, diuretics, etc.) Reauthorization: Documentation from provider indicating improvement in condition as evidenced by improvement of symptoms and showing member is being monitored for adverse effects (e.g. supine hypertension).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

DUPIXENT

Products Affected

- DUPIXENT PEN SUBCUTANEOUS PEN INJECTOR 200 MG/1.14 ML, 300 MG/2 ML
- DUPIXENT SYRINGE SUBCUTANEOUS SYRINGE 200 MG/1.14 ML, 300 MG/2 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with any other monoclonal antibody that can be used to treat the same indication as the requested medication
Required Medical Information	COPD-Initial: Approve if the member has dx of inadequately controlled, eosinophilic phenotype of COPD meeting all A, B, C, and D: A) Labs submitted showing a blood eos at least 300 cells per microliter taken within previous 6 wks or prior to mAb therapy, B) FEV1/FVC ratio less than 0.7 and FEV1 at least 30% but not more than 80% post-bronchodilator, C) Currently treated with triple or dual therapy (LABA/LAMA/ICS or LAMA/LABA) for at least 3 mos, AND D) Has signs or symptons of chronic bronchitis for at least 3 mos in the previous 12 mos. Has experienced COPD exacerbations in the past 12 months meeting A or B: A) 2 or more episodes requiring tx with oral corticosteroids or antibiotics OR B) episode required hospitalization. Provider attests member will continue dual or triple therapy while on requested medication. Reauthorization: Approve if member has responded positively to therapy and continues to use in combination with dual or triple therapy inhaler. CSU-Initial: Approve if member has diagnosis w/ documentation of the following (A, B, and C): A) Urticaria present for no less than 6 wks, B) Member experiences spontaneous occurence of wheals or hives that are pruritic in nature, not painful, more than 3 days per wk, AND C) Symptoms persist despite taking doses of second generation H1-antihistamines (e.g. cetirizine) for at least two wks. EOE-Initial: Approve if member weighs at least 15kg and dx is confirmed by endoscopic biopsy showing at least 15 intraepithelial eosinophils per hpf, secondary causes have been ruled out, and member has tried and failed 8 wks therapy with a rx strength PPI (i.e. omeprazole 40 mg). PN-Initial: Approve if member has experienced 6 wks of pruritus (chart doc req showing hx or signs of repeated scratching [i.e. lesions]. CSU/EOE/PN Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Age Restrictions	AD: 6 months and older, Asthma: 6 years of age and older, EoE: 1 year and older, CRSwNP/CSU: 12 years and older, COPD/PN: 18 years and older

PA Criteria	Criteria Details
Prescriber Restrictions	Must be prescribed by or in consultation with one of the following: Atopic Dermatitis/Prurigo Nodularis: Allergist, immunologist, or dermatologist. Asthma: Allergist, immunologist or pulmonologist. Chronic Rhinosinusitis with Nasal Polyps: Allergist, immunologist, or otolaryngologist. Eosinophilic Esophagitis: Allergist or gastroenterologist. COPD: Pulmonologist. CSU: Allergist, immunologist, or dermatologist.
Coverage Duration	12 months
Other Criteria	Atopic Dermatitis (AD): 6-23 months: Approve if member has tried and failed one prescription strength topical corticosteroid except where face, eyes, or genitalia are impacted. 2 years and older: Approve if member has tried and failed one prescription strength topical corticosteroid OR tacrolimus ointment. Asthma: Approve if member meets i, ii, and iii: i) Member has a blood eosinophil at least 150 cells per microliter w/in prior 6 weeks OR has oral CS-dependent asthma, ii) Member has received both an ICS AND an adjunct maintenance medication (i.e. montelukast) (Note: Exception to the requirement for a trial of an asthma maintenance medication can be made if already established on monoclonal antibodies used concomitantly w/an ICS, AND iii) Asthma is uncontrolled defined by member experiencing one of the following (A, B, C, D, or E): A) 2 or more asthma exacerbations requiring treatment with systemic CS in last 12 months, B) 1 or more asthma exacerbations requiring hospital or ED visit in last 12 months, C) Member has a FEV1 less than 80 percent predicted (90 percent for 6-18 years), D) Member has an FEV1/FVC less than 0.80 (0.90 for 6-18 years), OR E) asthma worsens with tapering of oral CS. Reauthorization: Approve if member continues to receive tx with 1 ICS or 1 ICS-containing combo inhaler and has responded positively to treatment. CRSwNP-Initial: Approve if member is receiving treatment with an intranasal CS and experiencing rhinosinusitis symptoms like nasal obstruction, rhinorrhea, or reduction/loss of smell. Member must have received treatment within previous 2 yrs or has contraindication to systemic CS tx OR if member had prior surgery for nasal polyps. Reauthorization: Approve if member continues to receive tx with an intranasal CS and has responded positively to treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ELIGARD

Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has diagnosis of prostate cancer that is considered advanced. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

EMGALITY

Products Affected

- EMGALITY PEN
- EMGALITY SYRINGE SUBCUTANEOUS SYRINGE 120 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another injectable CGRP inhibitor
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Migraine Prevention-Initial: Approve if the member has a diagnosis of chronic migraine with or without aura based upon ICHD-3 criteria: Member has migraine-like or tension-type headaches occuring on 15 or more days/month for more than 3 months and on at least 8 days per month for greater than 3 months, fulfills any of the following A, B, or C: A) Members having migraine without aura has headaches with at least two of the four characteristics: unilateral location, pulsating quality, moderate or severe pain intensity, aggravation by or causing avoidance of routine physical activity (e.g., walking or climbin stairs) AND at least one of the following occurred during the headache: nausea and/or vomiting, photophobia and/or phonophobia, B) Members having migraine with aura has headaches with one or more of the following fully reversible aura symptoms: visual, sensory, speech and/or language, motor brainstem, retinal AND at least three of the following six characteristics: at least one aura symptom spreads gradually over greater than or equal to 5 minutes, two or more aura symptoms occur in succession, each individual aura symptom lasts 5-60 minutes, at least one aura symptom is unilateral, at least one aura symptom is positive, the aura is accompanied, or followed within 60 minutes by headache, or C) believed by the member to be migraine at onset and relieved by a triptan or ergot derivative. Provider

PA Criteria	Criteria Details
	attests the diagnosis is not better accounted for by another ICHD-3 diagnosis (i.e. medication overuse) and medication will not be used concomitantly with onabotulinumtoxin A (Botox). Episodic Cluster Treatment-Initial: Approve if the member has a diagnosis of episodic cluster headache based upon ICHD-3 criteria: severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes when untreated, with at least one of the following symptoms: a sense of reslessness or agitation, conjunctival injection and/or lacrimation, nasal congestion and/or rhinorrhea, eyelid edema, forehead and facial sweatingmiosis and/or ptosis. Cluster attacks occur with a frequency between one every other day and eight per day, and pain-free remission periods of at least 3 months between cluster attack periods). Provider attests the diagnosis is not better accounted for by another ICHD-3 diagnosis (i.e. medication overuse). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

EMSAM

Products Affected

- EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with serotonergic drugs (i.e. selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), clomipramine and imipramine, meperidine, tramadol, methadone, pentazocine, and propoxyphene), dextromethorphan, or carbamazepine. Members with pheochromocytoma or nursing mothers.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if member has a diagnosis of Major Depressive Disorder based on the following: A) Member has five or more of the following symptoms that have been present during the same two-week period and represent a change from previous functioning (Note: one of the symptoms is either depressed mood or loss of interest or pleasure): 1) depressed mood most of the day, nearly every day, 2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day, 3) significant weight loss when not dieting or weight gain (e.g. a change of more than 5% in a month), or change in appetite nearly every day, 4) insomnia or hypersomnia nearly every day, 5) psychomotor agitation or retardation nearly every day that are observable by others, 6) fatigue or loss of energy nearly every day, 7) feelings of worthlessness or excessive or inappropriate guilt, 8) diminished ability to think or concentrate, or indecisiveness, nearly every day, 9) recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attemmpt or a specific plan for committing suicide, B) The episode is not attributable to the psysiologoical effects of a substance or to another medical condition (i.e. serious medical illness or disability, financial hardships), AND C) The occurrence of the major depressive episode is not better explained by schizoaffective

PA Criteria	Criteria Details
	disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders. The member must have a trial and failure of two generic antidepressants used to treat the same indication prior to approval (i.e. sertraline concentrate, fluoxetine solution, citalopram solution, escitalopram solution). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENBREL

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SYRINGE
- ENBREL SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, targeted synthetic DMARDs, potent immunosuppressants, anti-interleukin monoclonal antibodies, or janus kinase inhibitors. Members with an active infection or sepsis.
Required Medical Information	Diagnosis. For PsA and PsO: Trial and failure or contraindiation to a preferrred ustekinumab product (Selarsdi, Yesintek), if age appropriate. For AS/JIA/JRA/RA : Trial and failure or contraindiation to a preferred adalimumab product (Hadlima, Simlandi) prior to approval.
Age Restrictions	RA/AS: 18 years and older
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: RA/AS/JIA/JRA: Rheumatologist. PsA: Rheumatologist or dermatologist.PsOs: Dermatologist.
Coverage Duration	12 months
Other Criteria	Rheumatoid Arthritis (RA)/Juvenile Rheumatoid Arthritis (JRA)-Initial: Approve if member has diagnosis of moderately to severely active disease and member has tried and failed a preferred adalimumab product (Hadlima, Simlandi). Polyarticular Juvenile Idiopathic Arthritis (PJIA)-Initial: Approve if member has diagnosis of moderately to severely active disease and member has tried and failed a preferred adalimumab product (Hadlima, Simlandi). Plaque Psoriasis (PsO)-Initial: Approve if the member has chronic moderate to severe disease and member meets A, B, or C: A) Member is 18 years of age or older and has tried and failed a preferred adalimumab product (Hadlima, Simlandi) OR B) Member is 6 - 17 years and has tried and failed a preferred ustekinumab product (Selarsdi, Yesintek), OR C) Member is 2 - less than 6 years. Ankylosing Spondylitis (AS): Approve if the member has signs and symptoms of active disease (i.e. back pain and stiffness in the lower back and hips, neck pain and fatigue, skin rashes) and member has tried and failed a preferred adalimumab product (Hadlima, Simlandi). Psoriatic Arthritis(PsA)/Juvenial Psoriatic Arthritis (JPsA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following

PA Criteria	Criteria Details
	(documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD) AND meets A, B, or C: A) Member is 18 years of age or older and has tried and failed a preferred adalimumab product (Hadlima, Simlandi) OR B) Member is 6 - 17 years and has tried and failed a preferred ustekinumab product (Selarsdi, Yesintek), OR C) Member is 2 - less than 6 years. For all indications, prescriber must attest to performing a latent tuberculosis (TB) test prior to starting treatment and monitoring for active TB throughout treatment even if initial latent TB test is negative. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENVARSUS XR

Products Affected

- ENVARSUS XR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a transplant specialist or nephrologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member will be using the requested medication for kidney transplant rejection prophylaxis AND member has tried and failed or has an intolerance to immediate-release tacrolimus (i.e. unable to achieve clinically appropriate concentration levels) or provider has submitted documentation with rationale why tacrolimus immediate-release is not expected to provide the same result. Requested medication must be used in combination with other immunosuppressants. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Requested medication will continue to be used in combination with other immunosuppressants. Note: B versus D determination will me made prior to application of clinical criteria
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Dravet Syndrome-Initial: Approve if the member is at least 1 year of age has tried or is concomitantly receiving at least two other antiepileptic drugs or if the patient has tried or is concomitantly receiving one of Diacomit or clobazam or Fintepla. Lennox Gastaut Syndrome-Approve if the member is at least 1 year of age and has tried or is concomitantly receiving at least two other antiepileptics drugs. Tuberous Sclerosis Complex-Initial: Approve if the member has tried or is concomitantly receiving at least two other antiepileptic drugs. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPOETIN ALFA

Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a surgeon, nephrologist, hematologist, an oncologist, gastroenterologist, hepatologist, transplant physicisan, or infectious disease physician
Coverage Duration	6 months
Other Criteria	Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit). If the drug is determined not to be ESRD-related, criteria applies. Anemia in Chronic Kidney Disease (CKD)-Initial: Member must not be on dialysis. Hemoglobin (Hgb) must be less than 10 g/dL in adults or less than or equal to 11 g/dL for children. Reauthorization: Approve if member is currently on erythropoiesis-stimulating agent (ESA) and Hgb is less than or equal to 12 g/dL. Chemotherapy-induced Anemia-Initial: Approve if member is currently receiving myelosuppressive chemotherapy for non-myeloid malignancy and has documentation of a minimum of 2 more months of therapy planned. Hgb is less than 10 g/dL or if currently on ESA, Hgb is less than or equal to 12 g/dL. Reauthorization: Approve if member is benefitting from therapy and has documentation of a minimum of 2 more months of therapy planned. RBC transfusion Reduction in Surgery: Approve if Hgb is 10-13 g/dL and member is at high risk for perioperateive transfusion due to significant anticipated blood loss. Surgery must be elective, non-cardiac, and non-vascular in nature and member is unwilling or unable to donate autologous blood prior to surgery. All indications must have a requested dose that falls within the recommended dosing guidelines from the manufacturer.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

EPRONTIA

Products Affected

- *topiramate oral solution*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact dosage form (i.e. tablet or capsule).
Age Restrictions	N/A
Prescriber Restrictions	Seizures: Prescribed by or in consultation with a neurologist. Migraine Prevention: Prescribed by or in consultation with a headache specialist or pain specialist.
Coverage Duration	12 months
Other Criteria	Seizures-Initial: Approve if the member has had a trial and failure or contraindication to two generic antiepileptic drugs (e.g. lamotrigine, topiramate) and meets either A or B: A) Member has partial-onset or primary generalized tonic-clonic seziures and medication will be used as monotherapy OR B) Member has partial-onset, primarcy generalized tonic-clonic seizures, or seizures that are associated with Lennox-Gastaut syndrome and medication will be used as adjunctive therapy. Migraine Prevention-Initial: Approve if member has a trial and failure to two medications used for migraine prevention (i.e. propranolol, divalproex sodium, metoprolol). For all indications, member must have documentation supporting the inability to swallow an intact tablet or capsule prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ERGOT ALKALOIDS

Products Affected

- *dihydroergotamine injection*
- *dihydroergotamine nasal*

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension. Ischemic heart disease (e.g. angina pectoris, history of myocardial infarction, or documented silent ischemia), or clinical symptoms or findings consistent with coronary artery vasospams including Prinzmetal's variant angina. Concomitant use with potent CYP3A4 inhibitors, such as protease inhibitors and macrolide antibiotics (e.g. ritonavir, nelfinavir, erythromycin, clarithyromycin, ketoconazole, itraconazole, etc). Use within 24 hours of ergotamine-containing or ergot-type medications or methysergide. Treatment of hemiplegic or basilar migraines. Known peripheral arterial disease, sepsis, following vascular surgery, and severely impaired hepatic or renal function. Pregnancy or nursing mothers. Concomitant use with peripheral and central vasoconstrictors
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has diagnosis of acute migraine with or without aura. Must not be used for the prophylactic therapy of migraines. Must have trials of two different formulary triptans with inadequate responses or significant side effects/toxicity unless contraindicated. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of metastatic basal cell carcinoma as determined by an FDA-approved test. Member must have locally advanced disease that has recurred following surgery or member is not a candidate for surgery or radiation. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ERLEADA

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of prostate cancer and member will be taking requested medication in combination with a gonadotropin-releasing hormone (GnRH) analog or member has had a bilateral orchiectomy. Member must meet either A or B: A) Member's disease is castration sensitive AND metastatic, or B) Member's disease is castration resistant AND non-metastatic. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ERLOTINIB

Products Affected

- *erlotinib oral tablet 100 mg, 150 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Pancreatic Cancer-Initial: Approve if the member has locally advanced, unresectable or metastatic disease. Member must use the requested medication in combination with gemcitabine. Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as determined by an FDA-approved test. Member must be receiving therapy as first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

EUCRISA

Products Affected

- EUCRISA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with an allergist, immunologist, or dermatologist.
Coverage Duration	12 months
Other Criteria	Atopic Dermatitis-Initial: 3-23 months: Approve if member has tried and failed one prescription strength topical corticosteroid except where face, eyes, or genitalia are impacted. 2 years and older: Approve if member has tried and failed one prescription strength topical corticosteroid (except where face, eyes, or genitalia are impacted) AND one topical calcineurin inhibitor (i.e. pimecrolimus cream or tacrolimus ointment) unless the member has a documented intolerance or contraindication to aforementioned therapies. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EULEXIN

Products Affected

- EULEXIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of prostate cancer and the member will be using the medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the member has had a bilateral orchiectomy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

EVEROLIMUS

Products Affected

- *everolimus (antineoplastic) oral tablet*
- *everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Initial: Approve if member is a postmenopausal woman with advanced hormone receptor-positive (HR+), HER2-negative breast cancer AND medication will be used in combination with exemestane after failure of treatment with letrozole or anastrozole. PNET and NET-Initial: Approve if member has a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) OR diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. RCC-Initial: Approve if member has a diagnosis of advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib (Sutent) or sorafenib (Nexavar). TSC-Initial: Approve if member has diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery. TSC Associated SEGA-Initial: Approve if member requires therapeutic intervention but cannot be curatively resected. TSC-associated partial-onset seizures-Initial: Approve. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EXXUA

Products Affected

- EXXUA ORAL TABLET EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
Exclusion Criteria	Prolonged QTc interval greater than 450 msec at baseline or congenital long QT syndrome
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FASENRA

Products Affected

- FASENRA PEN
- FASENRA SUBCUTANEOUS SYRINGE 10 MG/0.5 ML, 30 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody (i.e Dupixent, Cinqair, Nucala, Tezspire, or Xolair)
Required Medical Information	Diagnosis
Age Restrictions	EGPA-18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other Criteria	Asthma-Initial: Member must have a diagnosis of eosinophilic phenotype severe asthma with a peripheral blood eosinophil count of greater than or equal to 150 cells/uL within the previous 6 weeks and prior to treatment with any monoclonal therapy. Member meet both of the following criteria: 1) Member has received combination therapy with an inhaled corticosteroid AND one additional controller/maintenance medication (e.g. inhaled LABA, inhaled LAMA), AND 2) Member's asthma is uncontrolled prior to any monoclonal antibody therapy definied by one of the following A, B, C, D, or E: A) member experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, B) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, C) Member has a FEV1 less than 80 percent predicted (90 percent for adolescents), D) Member has an FEV1/FVC less than 0.80 (0.90 for adolescents), OR E) Member's asthma worsens upon tapering of oral corticosteroid therapy. Reauthorization: The member has responded to requested therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND member continues to receive therapy with an inhaled corticosteroid.

PA Criteria	Criteria Details
	EGPA-Initial: Approve if member meets all of the following A, B, C, D, and E (documenation required): A) Has relapsed or refractory disease, B) Trial and failure or contraindication to treatment with prednisone or prednisolone at a maximally tolerated dose, C) Positive history of asthma, D) Blood eosinophil level of 10 percent or absolute eosinophil count greater than 1000 cells/uL, E) 2 or more criteria that are typical of EGPA (i.e. neuropathy, glomerulonephritis, palpable purpura, etc) OR histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FELBAMATE (SUSPENSION)

Products Affected

- *felbamate oral suspension*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has had a trial and failure or contraindication to two generic antiepileptic drugs (e.g. lamotrigine, topiramate) and meets either A or B: A) Member is an adult with partial seziures, with or without generalization, and medication will be used as monotherapy or adjunctive therapy OR B) Member is a child partial and generalized seizures that are associated with Lennox-Gastaut syndrome. Medication will be used as adjunctive therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FENTANYL (TRANSDERMAL)

Products Affected

- *fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr*

PA Criteria	Criteria Details
Exclusion Criteria	Acute (i.e. non-chronic) pain
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Members with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet the following criteria: Approve if the member is not using the medication to treat acute pain. Must be used for the management of severe and persistent pain that requires an extended treatment period in a member who has been taking an opioid. Must have a history of at least one week of one short acting opioid analgesic (e.g., tramadol or hydrocodone/acetaminophen). Must provide clinical rationale that the expected benefits specific to the member have been weighed against risks before initiating therapy (e.g. non-opioid therapies have been tried as appropriate for the member based on the provider's assessment). Provider must attest to chart documentation of a treatment plan (including goals for pain and function) that includes reassessment at regularly scheduled intervals. Must provide an attestation of each of the following: the member has been counseled on the risks of opioid use, the Prescription Drug Monitoring Program (PDMP) has been reviewed, the member can safely take the requested regimen based on their opioid history, and that non-opioid therapies and are being used with opioid therapy as appropriate based on the prescriber's assessment. Reauthorization: must have documentation from prescriber indicating improved pain control and improved level of functioning and must provide

PA Criteria	Criteria Details
	an attestation of each of the following: the member has been counseled on the risks of opioid use, the PDMP has been reviewed.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FINGOLIMOD

Products Affected

- *fingolimod*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS). Recent myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure. History of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless member has a pacemaker. Baseline QTc interval greater than or equal to 500 msec. Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or an MS specialist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member is at least 10 years of age and has a diagnosis of relapsing multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Use of monoamine oxidase inhibitors within 14 days
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an neurologist
Coverage Duration	12 months
Other Criteria	Must have a baseline echocardiogram to evaluate for valvular heart disease and pulmonary arterial hypersion. For members with established valvular heart disease and/or pulmonary arterial hypertension, attestation from the provider assessing the risks and benefits of therapy must be documented. Dravet Syndrome-Initial: Approve if the member is at least 2 years of age has a trial and failure of or contraindication to cannabidiol (Epidiolex) and one other generic antiepileptic medication. Lennox Gastaut Syndrome-Approve if the member is at least 2 years of age and has tried or is concomitantly receiving at least two other antiepileptics drugs. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FLUCYTOSINE

Products Affected

- *flucytosine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consulation with an infectious disease specialist
Coverage Duration	6 weeks
Other Criteria	Initial: Approve if member has a serious infection caused by a susceptible strain of Candida or Cryptococcus (documentation required). Member will be using the requested medication with another antifungal agent (i.e. amphotericin B). Reauthorization: Additional authorizations for treatment are made on a case-by-case basis, are subject to the above criteria, and require chart documentation describing the previous response and clinical rationale for re-treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Renal Cell Carcinoma (RCC)-Initial: Approve if member has advanced disease that has relapsed or is refractory following two or more prior systemic therapies for the same indication (i.e. sunitinib, pazopanib). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FRUZAQLA

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Colorectal Cancer-Initial: Approve if the member has a diagnosis of metastatic colorectal cancer (mCRC) and meets all of the following A, B, and C: A) Member has been previously treated with fluoropyrimidine- (e.g., 5-fluorouracil, capecitabine), oxaliplatin-, and irinotecan-based chemotherapy, B) an anti-VEGF therapy (e.g. bevacizumab), AND C) if member has RAS wild-type (i.e. KRAS and NRAS mutation negative) and medically appropriate, an anti-EGFR therapy (e.g. cetuximab (Erbitux), panitumumab (Vectibix). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FYCOMPA

Products Affected

- FYCOMPA ORAL SUSPENSION
- *perampanel oral tablet 10 mg, 12 mg, 2 mg, 4 mg, 6 mg, 8 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, For suspension, must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has had a trial and failure or contraindication to two generic antiepileptic drugs (e.g. lamotrigine, topiramate) and meets either A or B: A) Member has partial seziures, with or without generalization, and medication will be used as monotherapy or adjunctive therapy OR B) Member has primary generalized tonic-clonic seizures and medication will be used as adjunctive therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GATTEX

Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

PA Criteria	Criteria Details
Exclusion Criteria	Active intestinal obstruction or active gastrointestinal malignancy
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of short bowel syndrome (SBS). Must provide date of bowel resection, baseline parenteral or intravenous nutrition (PN/IV) support scheduled including frequency and volume, colonoscopy if an adult or pediatric member with unexplained blood in the stool within 6 months before starting requested medication and at baseline (within 6 months) lab monitoring of bilirubin, alkaline phosphatase, lipase, and amylase. Must be receiving PN or IV nutrition support at least 3 times weekly. Reauthorization: Documentation from provider indicating improvement in condition, that member has weaned off or decreased PN/IV requirements, the member had a colonoscopy (if appropriate) after 1 year of treatment and at least every 5 years after the first year, and the member is undergoing laboratory testing of bilirubin, alkaline phosphatase, lipase, and amylase every 6 months.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

GAVRETO

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older, Thyroid cancer-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an FDA-approved test. Thyroid cancer-Initial: Approve if the member has advanced or metastatic RET fusion-positive disease and meets both the following criteria A and B: A) the disease is radioactive iodine-refractory (if radioactive iodine is appropriate) and B) the disease requires treatment with systemic therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member meets either A or B: A) Member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) where the member will be using the requested medication as first-line therapy and whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B) Member has metastatic, squamous NSCLC that has progressed after platinum-based chemotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GLATIRAMER

Products Affected

- *glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of relapsing forms of multiple sclerosis (RRMS). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- *liraglutide*
- MOUNJARO
- OZEMPIC SUBCUTANEOUS PEN INJECTOR 0.25 MG OR 0.5 MG (2 MG/3 ML), 1 MG/DOSE (4 MG/3 ML), 2 MG/DOSE (8 MG/3 ML)
- RYBELSUS
- TRULICITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of Type II Diabetes Mellitus (T2DM) confirmed by one of the following for the member within the previous 12 months (documentation required): A) Hemoglobin A1c (A1C) greater than or equal to 6.5%, B) Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL after fasting for at least 8 hours, C) 2-Hour plasma glucose is greater than or equal to 200 mg/dL as part of an oral glucose tolerance test (75g of oral glucose is consumed after fasting for at least 8 hours), OR D) chart note documentation confirming T2DM diagnosis. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

GLUTAMINE

Products Affected

- *glutamine (sickle cell)*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Adakveo
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Initial: Member must have a diagnosis of sickle cell disease. Must have documentation the member has experienced at least 2 sickle cell-related vaso-occlusive crises within the last 12 months requiring a medical facility visit (e.g., emergency department, infusion center, or hospital). Chart documentation of medical facility visit is required. Must have an adequate trial of at least 90 days on oral hydroxyurea (e.g., hydroxyurea tablet) with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GOMEKLI

Products Affected

- GOMEKLI ORAL CAPSULE 1 MG, 2 MG
- GOMEKLI ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Neurofibromatosis Type 1 (NF1)-Initial: Member must plexiform neurofibromas (PNs) that are both of the following: inoperable and causing significant morbidity (e.g. disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction). Member must use the requested medication as monotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- *leuprolide subcutaneous kit*
- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Cancer, CPP: 12 months, Endometriosis: 6 months, Fibroids: 3 months
Other Criteria	For all diagnoses: Dose must not exceed FDA labeling for diagnosis requested including, but not limited to, appropriate formulation for diagnosis, strength, and duration.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GROWTH HORMONES

Products Affected

- OMNITROPE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test with inadequate response OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate 5.pt had a hypophysectomy. Cont-pt responding to therapy
Age Restrictions	N/A
Prescriber Restrictions	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Prader Willi (initial for child/adult and cont tx in adults), SGA (initial) - prescribed by or in consultation with an endocrinologist.
Coverage Duration	ISS - 6 mos initial, 12 months cont tx, others 12 mos
Other Criteria	GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either

PA Criteria	Criteria Details
	childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy.Cont Tx for PW in child/adolescents and TS - prescriber confirms response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HERNEXEOS

Products Affected

- HERNEXEOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test. Member must have prior trial and failure of systemic therapy (e.g. platinum-based chemotherapy). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Initial: Approve if member has meets either A or B: A) Member has a diagnosis of locally advanced or metastatic disease that meets i, ii, and iii: i) Disease is PIK3CA-mutated, HR-positive, and HER2-negative as detected by an FDA-approved test, ii) Medication will be used in combination iwth inavolisib (Itovebi) and fulvestrant, iii) Disease is endocrine-resistant as determined following recurrence on or after completing adjuvant endocrine therapy OR B) Member has a diagnosis of advanced or metastatic disease that meets i, ii, and iii: i) Disease is hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative disease as detected by an FDA-approved test, ii) member had a trial of Verzenio or Kisqali prior to approval and member meets either 1 or 2: 1) Requested medication will be used in combination with an aromatase inhibitor as initial endocrine-based therapy (e.g. anastrozole, exemestane, letrozole) OR 2) Requested medication will be used with fulvestrant in members with disease progression following endocrine therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IBTROZI

Products Affected

- IBTROZI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has NSCLC that is ROS-1 positive as determined by an FDA-approved test AND is locally advanced or metastatic. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Philadelphia Chromosome-positive (Ph+) Acute Lymphoblastic Leukemia (ALL)-Initial: Approve if member meets one of the following A, B, or C: A) Approve if member has newly diagnosed Ph+ ALL AND medication will be used in combination with chemotherapy, B) Member has T315I-positive ALL, OR C) Requested medication will be used as monotherapy in members for whom no other TKIs are indicated. Chronic Myeloid Leukemia (CML)-Approve if member meets one of the following A, B, or C: A) Member has chronic phase (CP) CML with resistance or intolerance to at least two prior kinase inhibitors B) Member has Accelerated phase (AP) or blast phase (BP) CML for whom no other kinase inhibitors are indicated or C) Member has T315I-positive CML (chronic, accelerated, or blast phase). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Member must have a confirmed diagnosis of acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test. Member must have relapsed or refractory disease from prior treaments for the same indication. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMATINIB

Products Affected

- *imatinib oral tablet 100 mg, 400 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase-Approve. Ph+ CML in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy-Approve. Relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL)-Approve. Newly diagnosed Ph+ ALL-Approve if member is a pediatric patient AND medication will be used in combination with chemotherapy. Myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements-Approve for adult members. Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown-Approve for adult members. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)-Approve for adult members who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) OR members with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown. Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)-approve for adult members. Gastrointestinal Stromal Tumors (GIST)-Approve if member has Kit (CD117) positive unresectable and/or metastatic, malignant tumors OR if requested medication will be used as adjuvant treatment for adult members following resection of Kit (CD117) positive GIST. Reauthorization:

PA Criteria	Criteria Details
	Member has responded positively to therapy as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMBRUVICA

Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Graft versus Host Disease (cGVHD)- Initial: Approve if the patient has tried one or more conventional systemic treatments for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus). Chronic Lymphocytic Leukemia (CLL)/Small lymphocyctic lymphoma (SLL) with or without 17p deletion-Approve. Waldenstrom macroglobulinemia (WM)-Approve. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMKELDI

Products Affected

- IMKELDI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, Must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase-approve. Ph+ CML in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy-approve. Relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL)-approve. Newly diagnosed Ph+ ALL-Approve if member is a pediatric patient AND medication will be used in combination with chemotherapy. Myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements-Approve for adult members. Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown-Approve for adult members. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)-Approve for adult members who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) OR members with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown. Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)-approve for adult members. Gastrointestinal Stromal Tumors (GIST)-Approve if member has Kit (CD117) positive unresectable and/or metastatic, malignant tumors OR if requested medication will be used as adjuvant treatment for adult members following resection of Kit (CD117) positive GIST. Reauthorization:

PA Criteria	Criteria Details
	Member has responded positively to therapy as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMPAVIDO

Products Affected

- IMPAVIDO

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, Sjogren-Larsson-Syndrome
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	30 Days
Other Criteria	Initial: Member must weigh greater than or equal to 30 kg (66 lbs) and have a diagnosis of one of the following confirmed using methods such as histopathology, parasite isolation by in vitro culture, polymerase chain reaction, molecular detection of parasite DNA, serologic testing (visceral leishmaniasis): (1) Visceral leishmaniasis due to Leishmania donovani, (2) Cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis, or (3) Mucosal leishmaniasis due to Leishmania braziliensis. Must have a trial and failure, contraindication or intolerance to Liposomal Amphotericin B prior to approval.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	Yes
Prerequisite Therapy Required	No

INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	Closed epiphyses, malignant neoplasia or history of malignancy. Concomitant use with growth hormone treatments. Secondary forms of IGF-1 deficiency, such as malnutrition, hypopituitarism, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. Premature babies or neonates.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency (SPIGFD) defined by all the following: 1) Height standard deviation score of -3.0 or less, 2) basal IGF-1 levels below the 2.5th percentile for age and gender, and 3) Growth hormone (GH) sufficiency (i.e. normal or elevated GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH. SPIGFD includes members with mutations in the GH receptor (GHR) gene/Laron's syndrome, post-GHR signaling pathway, and IGF-1 gene defects. Reauthorization: Confirmation that epiphyses have not closed and chart note documentation from the provider indicating the member's condition has improved while on the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

INLURIYO

Products Affected

- INLURIYO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has advanced or metatstatic breast cancer that is estrogen-receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, and estrogen receptor 1 (ESR1)-mutated based on an approved test. Member must have disease progression following at least one line of endocrine therapy (e.g., exemestane, letrozole). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Pending CMS Review

INLYTA

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Renal Cell Carcinoma (RCC)-Initial: Approve if the member has advanced disease and meets one of the following (A, B, or C): A) Member will be using the requested medication in combination with avelumab (Bavencio) as first-line therapy, B) Member will be using the requested medication in combination with pembrolizumab (Keytruda) as first-line therapy, OR C) Member will be using the requested medication as a single agent after failure of one prior systemic therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Myelodysplastic Syndromes (MDS)-Initial: Approve if the member has a diagnosis of MDS, including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed myelomonocytic leukemia (CMML), and intermediate-1, intermediate-2, adn high-risk internationanal prognostic scoring system groups.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-Initial: Approve if the member has a diagnosis of intermediate-2 or high-risk disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

IRESSA

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ITOVEBI

Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Member must have a diagnosis of endocrine-resistant, PIK3CA-mutated, hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or within 12 months of completing adjuvant endocrine therapy (i.e. tamoxifen, anastrozole, exemestane). Member must use requested medication in combination with palbociclib (Verzenio) and fulvestrant. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IVERMECTIN (ORAL)

Products Affected

- *ivermectin oral tablet 3 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Provider must attest medication will not be used for the treatment of COVID-19. Requested medication has not been approved for this use given no evidence of improving health outcomes for those infected with COVID-19 has been established in clinical trials.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

IVIG

Products Affected

- GAMASTAN
- GAMUNEX-C INJECTION SOLUTION 1 GRAM/10 ML (10 %)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

IWILFIN

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Neuroblastoma-Initial: Approve if the member meets all the following (A, B and C): A) Member has high-risk disease, B) The medication is being used to reduce the risk of relapse, AND C) Member has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy (e.g. dinutuximab). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	MF/PV-18 and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, hematologist, or transplant specialist
Coverage Duration	12 months
Other Criteria	Myelofibrosis-Initial: Approve if the member is an adult with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemica vera myelofibrosis and post-essential thrombocythemia myelofibrosis. Polycythemia Vera (PV)-Initial: Approve if the member has a diagnosis of PV and the member has tried and failed or has a contraindication to hydroxyurea (documentation required). Acute Graft versus Host Disease (aGVHD)-Initial: Approve if the member has tried and failed one systemic corticosteroid. Chronic Graft versus Host Disease (cGVHD)-Initial: Approve if the member has tried and failed one or two lines of systemic therapy prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAYPIRCA

Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Mantle Cell Lymphoma-Initial: Approve if the member has relapsed or refractory disease after a trial and failure of two prior lines of systemic therapy including one Bruton Tyrosine Kinase (BTK) inhibitor (i.e. Brukinsa, Imbruvica, Calquence). Chronic Lymphocytic Leukemia (CLL)/Small lymphocyctic lymphoma (SLL)-Initial: Approve if member has received at least two prior lines of therapy including one BTK inhibitor (i.e. Brukinsa, Imbruvica, Calquence) AND one B-Cell Lymphoma inhibitor (BCL-2 inhibitor) (i.e. Venclexta). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KALYDECO

Products Affected

- KALYDECO ORAL GRANULES IN PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications containing ivacaftor
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a cystic fibrosis specialist
Coverage Duration	12 months
Other Criteria	Initial: Must have a diagnosis of cystic fibrosis and documentation of one of the following: 1) One mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data OR 2) If the member's genotype is unknown, an FDA-cleared cystic fibrosis mutation test used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. Provider attestation liver function tests will be assessed prior to initiation of treatement, during the first 6 months of treatment, every 3 months for the next 12 months, then at least annually thereafter. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician, absent of toxicities, and provider attestation to monitor liver function tests at least annually.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KERENDIA

Products Affected

- KERENDIA ORAL TABLET 10 MG, 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	Adrenal insufficiency, concomitant use with strong CYP3A4 inhibitors.
Required Medical Information	Diagnosis. Heart Failure-Initial: Member must have chart note documentation of the following: LVEF greater than or equal to 40%, evidence of structural or functional heart disease, AND symptomatic heart failure (NYHA class II-IV). Laboratory documentation required showing member has: eGFR greater than 25 mL/minute/1.73 m2 AND serum potassium less than 5 mEq/L. Member must have a trial and failure or contraindication to a sodium glucose co-transporter-2 (SGLT2) inhibitor (i.e. dapagliflozin [Farxiga], empagliflozin [Jardiance]). Member must be on standard background medical therapy for HFmrEF or HFpEF, if appropriate (e.g. loop diuretics, ACE inhibitors, angiotensin receptor blockers). Members starting dose is appropriate for their current eGFR and serum potassium, and provider agrees to follow FDA labeled dosing regimen (based on lab work obtained 4 weeks after initiating treatment). Member will not be using the medication concomitantly with another mineralocorticoid receptor antagonist (e.g. spironolactone, eplerenone). Heart Failure-Reauthorization: Chart note documentation must be submitted showing the member has maintained a LVEF greater than or equal to 40%. Documentation from provider indicating stabilization or improvement in condition and attestation serum potassium and eGFR will continue to be monitored. Member continues to be on a maximally tolerated dose of standard therapy (e.g. loop diuretics, ACE inhibitors) or member has a contraindication or intolerance to these therapies.
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist, cardiologist, or endocrinologist
Coverage Duration	12 months
Other Criteria	CKD with T2DM-Initial: At initiation of therapy must meet all of the following: 1) estimated glomerular filtration rate (eGFR) greater than or

PA Criteria	Criteria Details
	equal to 25 mL/min/1.73m2 AND 2) urinary albumin-to-creatinine ratio (UACR) of greater than or equal to 30mg/g AND 3) a serum potassium of less than or equal to 5mEQ/L. Must currently be receiving maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless there is a contraindication or significant side effect/toxicity to ACE or ARB therapy. CKD with T2DM-Reauthorization: Documentation from the provider that the member's condition has stabilized or improved based upon the prescriber's assessment while on therapy and/or attestation from provider that serum potassum is being monitored while on therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KESIMPTA

Products Affected

- KESIMPTA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Active hepatitis B infection, concomitant use with other disease-modifying agents used for multiple sclerois
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has diagnosis of a relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Must have had inadequate response or intolerance to ONE of the following: dimethyl fumarate, fingolimod, teriflunomide, or glatiramer. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KISQALI

Products Affected

- KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast cancer-Initial: Approve if member has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease and meets either A or B: A) Member has early disease (i.e. stage II and III) at high risk of recurrence AND medication will be used as adjuvant treatment in combination with an aromatase inhibitor (i.e. anastrozole, exemestane, letrozole) OR B) Member has advanced or metastatic disease AND medication will be used in combination with either i or ii: i) an aromatase inhibitor as initial endocrine-based therapy (i.e. anastrozole, exemestane, letrozole) OR ii) fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

KOSELUGO

Products Affected

- KOSELUGO ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Neurofibromatosis Type 1 (NF1)-Initial: Member must plexiform neurofibromas (PNs) that are both of the following: inoperable and causing significant morbidity (e.g. disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction). Member must use the requested medication as monotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KRAZATI

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has a diagnosis of locally advanced or metastatic NSCLC and meets both of the following A and B: A) Disease has a KRAS G12C-mutation as determined by an FDA-approved test AND B) Member has been previously treated with at least one systemic regimen (i.e. bevacizumab, cisplatin, carboplatin, docetaxel). Colorectal Cancer (CRC)-Initial: Approve if member has a diagnosis of locally advanced or metastatic CRC and meets all criteria A, B, and C: A) Disease has a KRAS G12C-mutation as determined by an FDA-approved test, B) Member has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, AND C) Medication will be used in combination with cetuximab.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LAPATINIB

Products Affected

- *lapatinib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast cancer-Initial: Approve if the member has a diagnosis of breast cancer whose tumors overexpress the human epidermal growth factor receptor 2 (HER2) and meets either A or B: A) Member is postmenopausal with metastatic, hormone receptor-positive (HR+) disease AND requested medication will be used in combination with letrozole OR B) Member has advanced or metastatic disease after receiving prior therapy with all the following i, ii, and iii: i) a taxane, ii) an anthracycline, AND iii) trastuzumab AND will be using the requested medication in combination with capecitabine. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LAZCLUZE

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 Months
Other Criteria	Initial: Approve if member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meets all the following A, B, and C: A) Disease is positive for epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test, B) Requested medication will be used as a first-line treatment in combination with amivantamab, AND C) Provider attests anticoagulant prophylaxis will be administered for the first four months of treatment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LENALIDOMIDE

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Mantle Cell Lymphoma (MCL)-Initial: Approve if the member has relapsed or progressed after bortezomib (Velcade) and one other therapy. Follicular lymphoma (FL) and Marginal Zone Lymphoma (MZL)-Initial: Approve if the member has been previously treated and will be using the requested medication in combination with rituximab. Multiple myeloma (MM)-Initial: Approve if the member has a diagnosis of MM and will be using the requested medication in combination with dexamethasone OR as maintenance following an autologous hematopoietic stem cell transplantation (auto-HSCT). Myelodysplastic Syndromes (MDS)-Initial: Approve if the member has transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q abnormality with or without addition cytogenetic abnormalties as detected by an FDA-approved test. For all diagnoses: Member must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and member must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LENVIMA

Products Affected

- LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X2), 20 MG/DAY (10 MG X 2), 24 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Differentiated Thyroid Cancer (DTC)-Initial: Member must have locally recurrent or metastatic, progressive, radioactive iodine-refractory disease AND medication will be used as monotherapy. Renal Cell Carcinoma (RCC)-Initial: Approve if the member has advanced disease and meets either A or B: A) Medication will be used as a first line treatment AND will be used in combination with pembrolizumab OR B) Medication will be used as second line treatment following one prior anti-angiogenic therapry AND will be used in combination with everolimus. Endometrial Carcinoma (EC)-Initial: Approve if the patient meets all the following criteria (A, B, C, and D): A) Member has advanced disease that is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H) as determinded by an FDA-approved test, B) Member had disease progression following prior systemic therapy in any setting, C) Medication will be used in combination with pembrolizumab (Keytruda), AND D) Member is not a candidate for curative surgery or radiation. Hepatocellular Carcinoma (HCC)-Initial: Approve. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LEUKERAN

Products Affected

- LEUKERAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of chronic lymphatic leukemia (CLL) or malignant lymphomas including lymphosarcoma, giant follicular lymphoma, and Hodgkins disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIDOCAINE PATCH

Products Affected

- *dermacinrx lidocan*
- *lidocaine topical adhesive patch,medicated 5 %*
- *lidocan iii*
- *lidocan iv*
- *lidocan v*
- *tridacaine ii*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if member has diagnosis of pain associated with post-herpetic neuralgia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, oncologist, infectious disease physician, or transplant physician
Coverage Duration	2 months
Other Criteria	Initial: Member must have a diagnosis of cytomegalovirus (CMV) infection/disease and meet all the following A, B, C: A) Member weighs greater than or equal to 35kg, B) Member is post-transplant, including members who have received a solid organ transplant or hematopoietic stem cell transplant, and C) Disease is refractory to treatment (with or without genotype resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet. Must have chart documentation of at least ONE of the following: cytomegalovirus (CMV) DNA level in whole blood or plasma that has not decreased by greater than or equal to 1 log10 (e.g., a 10 fold decrease, reduction by 90%) after 14 days of antiviral therapy at the treatment dose OR dose limiting toxicity preventing the continuation of current antiviral therapy (e.g. bone marrow suppression, renal toxicity). Must not be used concomitantly with ganciclovir or valganciclovir. Must not have CMV disease involving the central nervous system, including the retina. Reauthorization: Must have chart documentation from the provider that the member's condition has improved based upon the prescriber's assessment while on therapy or the member continues to benefit from therapy. For requests for doses that exceed 400mg twice daily: must be administered with carbamazepine, phenytoin, or phenobarbital AND must follow recommended dosing in the prescribing information.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LONG ACTING OPIOIDS

Products Affected

- *buprenorphine*
- *methadone intensol*
- *methadone oral concentrate*
- *methadone oral solution 10 mg/5 ml, 5 mg/5 ml*
- *methadone oral tablet 10 mg, 5 mg*
- *methadose oral concentrate*
- *morphine oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if member meets all of the following A, B, C, D, and E: A) patient is not opioid naive, B) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, C) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), D) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND E) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell disease or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member meets either A or B: A) Member has a diagnosis of gastric or gastroesophageal junction adenocarcinoma AND has been previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy OR B) Member has a diagnosis of metastatic colorectal cancer and meets either i or ii: i) medication will be used as a single agent OR ii) medication will be used in combination with bevacizumab when member has been previously treated with a fluropyrimidine-, oxaliplatin-, AND irinotecan-based chemotherapy, an anti-VEGF biological therapy, AND if the tumors are wild-type RAS (KRAS wild type and NRAS wild type) as determined by an FDA-approved test, an anti-EGFR therapy.Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

LORBRENA

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease that is anaplastic lymphona kinase (ALK) positive as detected by an FDA approved test. Member must have a trial and failure of alectinib (Alecensa) prior to approval or a medical reason as to why it cannot be started or continued. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LUMAKRAS

Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Metastatic Colorectal Cancer (mCRC)-Approve if member meets all the following A, B, and C: A) Member has diagnosis of KRAS G12C-mutated mCRC as determined by an FDA-approved test, B) Member will be receiving requested medication in combination with panitumamab (Vectibix), and C) Member has received prior treatement with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYNPARZA

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Initial: Approve if the member has a deleterious or suspected deleterious gBRCAm (germline BRCA-mutated), HER-2 negative disease as confirmed by an FDA-approved test and meets either A or B: A) Member has high-risk, early disease. Member has been treated with neoadjuvant or adjuvant chemotherapy. Medication will be used as adjuvant treatment. OR B) Member has metastatic disease and has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. If member is hormone receptor (HR-) positive, member should have also been treated with a prior endocrine therapy, if appropriate. Pancreatic Cancer-Initial: Approve if the member has a deleterious or suspected deleterious gBRCAm, metastatic disease that has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Member will be using medication as maintenance. therapy. Prostate Cancer: Initial: Approve if the member will be taking in combination with a gonadotropin-releasing hormone (GnRH) analog unless member had a bilateral orchiectomy and has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meets either A or B: A) Member has a deleterious or suspected deleterious germline or soatic homologous recombination repair (HRR) gene-mutation as determined by an FDA-approved test. Disease has progressed following prior treatment with enzalutamide (Nubeqa) or abiraterone OR B) Member has a deleterious or suspected deleterious BRCA-mutated germline AND medication will be

PA Criteria	Criteria Details
	used in combination with abiraterone and either prednisone or prednisolone. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYSODREN

Products Affected

- LYSODREN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrine specialist or oncologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of inoperable, functional or nonfunctional adrenal cortical carcinoma. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LYTGOBI

Products Affected

- LYTGOBI ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Cholangiocarcinoma-Initial: Approve if the member has intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an FDA-approved test. Member has unresectable locally advanced or metastatic disease. Member has received prior treatment with at least one systemic regimen (i.e. gemcitabine + cisplatin). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MARPLAN

Products Affected

- MARPLAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	2 months
Other Criteria	Initial: Approve if the member has a diagnosis of depression using the DSM-V criteria with the presence of five or more of the following symptoms in the same two-week period with at least one of the symptoms being depressed mood or loss of interest or pleasure: depressed mood most of the day, nearly every day, anhedonia, significant weight loss, insomnia or hypersomnia nearly every day, psychomotor agitation or retardation, fatigue or loss of energy nearly every day, feelings of worthlessness or excessive guilt, diminished ability to think or concentrate, or indecisiveness, recurrent thoughts of death, suicidal ideation, or a suicide attempt. Member must have tried and failed two other antidepressants prior to approval. Provider must attest the member will be continuously evaluated for clinical worsening, suicidality, or unusual changes in behaviors. Reauthorization: Additional authorizations for treatment are made on a case-by-case basis, are subject to the above criteria, and require chart documentation describing the previous response and clinical rationale for re-treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

MATULANE

Products Affected

- MATULANE

PA Criteria	Criteria Details
Exclusion Criteria	Members with inadequate marrow reserve as demonstrated by bone marrow aspiration.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of Stage III or IV Hodgkin's disease and medication will be used in combination with other anticancer medications (i.e. MOPP regimen including mechlorethamine, vincristine, procarbazine, and prednisone). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MAVYRET

Products Affected

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Genotype (including unknown)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEGESTROL

Products Affected

- *megestrol oral suspension 400 mg/10 ml (40 mg/ml), 625 mg/5 ml (125 mg/ml)*
- *megestrol oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight gain for cosmetic reasons.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKINIST

Products Affected

- MEKINIST ORAL RECON SOLN
- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	Members with colorectal cancer
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma-Initial: Approve if member has a diagnosis of unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test and member meets either A, B, or C: A) Member is treatment-naive and medication will be used as monotherapy, B) Member will be using the medication in combination with dabrafenib (Tafinlar), OR C) Member has lymph node involvement following complete resection and medication will be used as adjuvant treatment in combination with dabrafenib (Tafinlar). Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if member has a diagnosis of metastatic NSCLC with BRAF V600E mutations as detected by an FDA-approved test and medication will be used in combination with dabrafenib (Tafinlar). Anaplastic Thyroid Cancer (ATC)-Initial: Approve if member has a diagnosis of locally advanced or metastatic ATC with BRAF V600E mutations as detected by an FDA-approved test and there are no satisfactory locoregional treatment options available for the member. Medication must be used in combination with dabrafenib (Tafinlar). Solid Tumors-Initial: Approve if member has unresectable or metastatic solid tumors with BRAF V600E mutations as detected by an FDA-approved test. Member's disease has progressed following prior treatment and now have no satisfactory alternative treatment options. Medication must be used in combination with dabrafenib (Tafinlar). Low-Grade Glioma (LGG)-Initial:

PA Criteria	Criteria Details
	Approve if member has LGG with BRAF V600E mutations as detected by an FDA-approved test and disease requires systemic therapy. Medication must be used in combination with dabrafenib (Tafinlar).Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma-Initial: Approve if the member has unresectable or metastatic disease with a BRAF V600E or V600K mutation as detected by an FDA-approved test AND requested medication will be used in combination with encorfenib (Braftovi). Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if member has metastatic disease with a BRAF V600E mutation as detected by an FDA-approved test AND requested medication will be used in combination with encorfenib (Braftovi). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEMANTINE

Products Affected

- *memantine oral capsule,sprinkle,er 24hr*
- *memantine oral solution*
- *memantine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MERCAPTOPURINE SUSPENSION

Products Affected

- *mercaptopurine oral suspension*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if member has a diagnosis of Acute Lymphoblastic Leukemia (ALL) and will be using the requested medication as a part of a combination chemotherapy maintenance regimen. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

METHYLERGONOVINE

Products Affected

- *methylergonovine oral*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

METYROSINE

Products Affected

- *metyrosine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of pheochromocytoma and member has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MIFEPRISTONE

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome
Coverage Duration	12 months
Other Criteria	Endogenous Cushing's Syndrome-Initial: Approve if the requested medication is being used to control hyperglycemia secondary to hypercortisolism in members who have type 2 diabetes mellitus or glucose intolerance and member meets either A, B, or C: A) Member is not a candidate for surgery or surgery has not been curative, B) member is awaiting surgery for endogenous Cushing's Syndrome, OR C) Member is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MODAFINIL

Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	12 months
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD)-Initial: Approve if the member is working a shift work schedule (i.e., unconventional work hours) and has symptoms of insomnia during the major sleep period and excessive sleepiness (including inadvertent sleep) during the major awake period. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-Approve. Excessive daytime sleepiness associated with Narcolepsy-Initial: Approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MODEYSO

Products Affected

- MODEYSO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of diffuse midline glioma (DMG) with a confirmed H2 K27M mutation as detected by an approved test using tumor tissue-based testing. Member must have disease progression after prior therapy. Current weight must be submitted prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MULTAQ

Products Affected

- MULTAQ

PA Criteria	Criteria Details
Exclusion Criteria	Permanent atrial fibrillation (sinus rhythm will never be restored), recently decompensated heart failure requiring hospitalization or Class IV heart failure, second or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjuction with a functioning pacemaker), bradycardia less than 50 bpm, concomitant use of a strong CYP3A inhibitor or drugs and herbal products that prolong the QT interval and may induce torsade de pointes, severe hepatic impairment, QTc Bazett interval greater than or equal to 500ms, pregnancy or nursing mothers
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member is in sinus rhythm and has a history of paroxymal or persistent atrial fibrillation (AF). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NAYZILAM

Products Affected

- NAYZILAM

PA Criteria	Criteria Details
Exclusion Criteria	Acute, narrow-angle glaucoma
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-Initial: Approve if the member is currently receiving maintenance antiepileptic medication(s). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and member is still receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NERLYNX

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Initial: Approve if member has HER-2-positive disease as detected by an FDA-approved test and meets either A or B: A) Member has early-stage disease and medication will be used as a single agent, for the extended adjuvant treatment to follow adjuvant trastuzumab-based therapy, OR B) Member has advanced or metastatic disease after receiving two or more prior anti-HER-2 based regimens in the metastatic setting and medication will be used in combination with capecitabine. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and member has not exceeded total treatment of 1 year when being ised for extended adjuvant treatment of early-stage breast cancer.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEXLIZET

Products Affected

- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applicable definitions for all diagnoses include the following: High-Intensity Statin-Defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher. Statin Intolerance-Defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while reciving separate trieals of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin. Heterozygous Familial Hypercholesterolemia (HeFH)-Initial: Approve if member has a diagnosis of HeFH and meets both A and B: A) Member has one of the following (documentation required) i, ii, iii, or iv: i) untreated LDL-C at least 190 mg/dL, ii) phenotypic confirmation (i.e. mutations at the LDLR, apo B, PCSK-9, or LDLRAP1 genes), iii) Dutch Lipid Netowrk criteria score greater than 5, OR iv) Simon Broome criteria meets threshold for definite or possible/probable AND B) Member meets 1 or 2: 1) Member has tried one high-intensity statin and LDL-C remains 70 mg/dL or higher OR b) Member is statin intolerant. Primary Hyperlipidemia-Initial: Approve if the member has a diagnosis of primary hyperlipidemia that is not associated with established CVD or HeFH and meets either A or B: A) Member tried one high-intensity statin for 8 weeks or longer and the LDL-C remains at least 70 mg/dL OR B) Member is statin intolerant. High-Risk CVD and Established CVD-Initial: Approve if the member meets either 1 or 2: 1) Member tried one high-intensity statin and the LDL-C remains at least 55 mg/dL OR B) Member is statin intolerant (including

PA Criteria	Criteria Details
	those not taking a statin) AND Member meets either A or B: A) Member is a high risk for a CVD event, but without established CVD (i.e. i.e family history of premature ASCVD, primary hypercholesterolemia (LDL-C 160--189), metabolic syndrome, CKD, chronic inflammatory conditions, history of premature menopause and and pregnancy-associated conditions that increase later ASCVD risk, high-risk races/ethnicities, lipid/biomarkers associated with increased ASCVD risk, and diabetes-specific high-risk features but without established CVD) OR B) Member has established CVD with chart documentation of one of the following events: Prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NILUTAMIDE

Products Affected

- *nilutamide*

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment or severe respiratory insufficiency
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Prostate cancer-Initial: Approve if the member had surgical castration for the treatment of metastatic prostate cancer (Stage D2). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Multiple Myeloma (MM)-Initial: Approve if the member has received at least one prior therapy for multiple myeloma and the requested medication will used in combination with lenalidomide and dexamethasone. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NITISINONE

Products Affected

- *nitisinone*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, a hematologist, a nephrologist, or a physician who specializes in the treatment of inherited metabolic disorders
Coverage Duration	12 months
Other Criteria	Hereditary Tyrosinemia, Type 1 (HT-1)-Initial: Approve if the member has a diagnosis of HT-1 confirmed by chart note documentation showing one of the following A, B, or C: A) newborn screening for HT-1 with a positive succinylacetone test (test result and reference range required), B) genetic test result showing fumarylacetoacetate hydrolase (FAH) gene mutation (test result and reference range required), OR C) elevated blood or urine succinylacetone or succinylacetoacetate (SA) level (test result and reference range required). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NIVESTYM

Products Affected

- NIVESTYM

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with filgrastim or pegfilgrastim products within seven days of dose
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, hematologist, or transplant specialist
Coverage Duration	6 months
Other Criteria	Members with cancer receiving chemotherapy: Approve if the member meets either A, B, or C: A) Member is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), B) Member is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the member has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR C) Member has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

NOVOFINE DIABETIC SUPPLIES

Products Affected

- NEEDLES, INSULIN DISP.,SAFETY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Clinical rationale why the member is unable to use the preferred product (i.e. BD Autoshield Duo Needle 5mm x 30G, BD Autoshield Duo Pen Needle 5mm x 30G) must be submitted.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of prostate cancer and member will be taking the requested medication with a gonadotropin-releasing hormone (GnRH) analog concurrently or had a bilateral orchiectomy and meets either A or B: A) Member has non-metastatic, castration resistant disease, OR B) Member has metastatic, castration sensitive disease and the medication is used in combination with docetaxel or as monotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUCALA

Products Affected

- NUCALA SUBCUTANEOUS AUTO-INJECTOR
- NUCALA SUBCUTANEOUS RECON SOLN
- NUCALA SUBCUTANEOUS SYRINGE 100 MG/ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	COPD-Concurrent use with Ohtuvayre, Dupixent, or another Anti-interleukin (IL) Monoclonal Antibody. All others-Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody.
Required Medical Information	COPD: Chart note doc and labs taken w/in the prev 6 wks or prior to mAb tx showing eos at least 300 cells/microL, FEV1/FVC ratio less than 0.7, and FEV1 at least 30 percent but no more than 80 percent post-bronchodilator. Currently treated w/ triple or dual therapy (LABA/LAMA/ICS or LAMA/LABA) at least 3 mos AND has signs or sx of chronic bronchitis for at least 3 mos in the prev 12 mos AND meets either: A) 2+ exac req tx w/short-acting bronchodilators and OCS in the prev yr, B) 1+ asthma exac req hosp. or ED visit in the prev yr, C) MMRC dyspnea grade at least 2, OR D) COPD Assess Test score at least 10. Provider attests member will continue dual/triple therapy. Reauth-Continues dual/triple therapy combo AND responded positively to therapy as determined by the prescribing physician.
Age Restrictions	Asthma-6 years of age and older. EGPA/Polyps/COPD-18 years of age and older. HES-12 years and older.
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: Asthma: Allergist, immunologist, or pulmonologist. EGPA: Allergist, immunologist, pulmonologist, or rheumatologist. HES: Allergist, immunologist, pulmonologist, rhematologist, or hematologist. CRSwNP: Allergist, immunologist, or otolaryngologist. COPD: Pulmonologist.
Coverage Duration	Initial-Asthma/EGPA/polyps/COPD-6 months, HES-8 months. 12 months continuation.
Other Criteria	Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (prior to tx with any anti-IL-5) AND has received combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting any anti-IL tx as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma

PA Criteria	Criteria Details
	exacer requiring hospitalization or ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has FEV1/FVC less than 0.80, or Pt's asthma worsens upon taper of oral corticosteroid therapy.NOTE:An exception to requirement for trial of 1 additional asthma controller/maintenance med can be made if pt has already received anti-IL-5 tx used concomitantly with an ICS.Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks or within 6 wks prior to tx w/any anti-IL-5 tx. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with any anti-IL-5 tx, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis w/nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan AND B)pt experienced 2 or more of the following sympt for at least 6 months:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 years, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy, continues to receive tx with an intranasal corticosteroid and has responded to tx.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with quinidine, quinine, or mefloquine. Members with a history of quinidine, guinine, or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions. Use with MAOI or within 14 days of stopping an MAOI. Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g. thiordazine or pimozide).
Required Medical Information	Diagnosis
Age Restrictions	Diagnosis
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Initial: 3 months Reauthorization: 12 months
Other Criteria	Pseudobulbar Affect (PBA)-Initial: Member must have a diagnosis of PBA supported by chart documentation of the following: involuntary outbursts of laughing and/or crying that are incongruous or disproportionate to the member's emotional state and documentation of a clinical work-up, including clinical rationale for the PBA diagnosis and exclusion of other possible conditions that could result in emotional lability (e.g. depression, bipolar disorder, schizophrenia, epilepsy). Must have underlying neurological disorder such amyotrophic lateral scelerosis, multiple scloerosis, Alzheimer's and related diseases, stroke, traumatic brain injury, or Parkinsonian Syndrome. Reauthorization: Must have documentation from provider indicating decrease in number of laughing and/or crying episodes as a result of therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUPLAZID

Products Affected

- NUPLAZID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Member must be using medication for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. Must provide clinical rationale for diagnosis and exclusion of other diagnoses (e.g., dementia with Lewy bodies, visual processing deficits/loss of visual acuity, infectious causes, a general medical condition including delirium, or psychiatric disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features). Must have tried to discontinue or reduce dose of any medication(s) that may cause or contribute to hallucinations and delusions (e.g., dopamine agonist, amantadine, monoamine oxidase B inhibitors, anticholinergics) or provide clinical rationale indicating why dose reduction or discontinuation of applicable medications would not be appropriate. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

NURTEC

Products Affected

- NURTEC ODT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Migraine-Initial: Approve if member has trials and failures of two different formulary triptans with inadequate responses or significant side effects/toxicity unless contraindicated (Note: Members intolerant to triptan during first trial are not required to trial a second triptan). Episodic Migraine Prevention-Initial: Approve if the member has a diagnosis of episodic migraine with or without aura based upon ICHD-3 criteria: Member has headaches occuring on greater than or equal to 4 but less than 15 days/month and meets the following A, B, or C: A) Member had five or more lifetime attacks, B) Headaches meet at least two of the four characteristics: unilateral location, pulsating quality, moderate or severe pain intensity, aggravation by or causing avoidance of routine physical activity (e.g., walking or climbin stairs) AND C) at least one of the following occurred during the headache: nausea and/or vomiting, photophobia and/or phonophobia. Provider attests the diagnosis is not better accounted for by another ICHD-3 diagnosis (i.e. medication overuse) and medication will not be used concomitantly with onabotulinumtoxin A (Botox). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OCTREOTIDE (INJECTABLE)

Products Affected

- *octreotide acetate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly: Prescribed by or in consultation with an endocrinologist. Carcinoid tumor, VIP-secreting tumor: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Acromegaly-Initial: Approve if the member has a confirmed diagnosis of acromegaly with elevated serum IGF-1 for age/gender (test results with reference range required) or elevated growth hormone level greater than or equal to 1 ng/mL during an oral glucose intolerance test (test result with reference range required). Member must have inadequate response to surgery or documentation that this therapy is inappropriate. Severe Diarrhea and Flushing-Initial: Approve if the member has severe diarrhea and flushing associated with a metatstatic carcinoid tumor. Profuse Watery Diarrhea-Initial: Approve if the member has profuse watery diarrhea associated with Vasoactive Intestinal Peptide Tumors (VIPomas). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Basal Cell Carcinoma (BCC)-Initial: Approve if the member has a diagnosis of BCC and meets either A or B: A) Member has recurrent disease following surgery or radiation therapy OR B) Member is not a candidate for surgery nor radiation therapy according to the prescribing physician. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	IPF: Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis: Prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	12 months
Other Criteria	Idiopathic Pulmonary Fibrosis (IPF)-Initial: Member must have FVC greater than or equal to 40% of the predicted value. Must have diffusing capacity for carbon monoxide (DLCO) 30% to 90% of predicted. IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP with all other diagnoses ruled out (e.g. domestic and occupational enviornmental exposures, connective tissue disease, and drug toxicity). Interstitial lung disease associated with systemic sclerosis-Initial: Approve if the FVC is greater than or equal to 40% of the predicted value. Must have DLCO 30% to 89% of predicted. Diagnosis is confirmed by high-resolution computed tomography (CT) with evidence of fibrosis. Member must meet the 2013 ACR/EULAR criteria for definite systemic sclerosis (total score of 9 or more). Chronic fibrosing interstitial lung disease (ILDs)-Initial: Approve if the member has progressive phenotype disease (defined as meeting one of the following criteria for disease progression in the previous 24 months despite treatement for ILD: FVC decline greater than or equal to 10%. FVC decline 5% to less than 10% and worsening of respiratory symptoms, FVC decline 5% to less than 10% and increased extent of fibrosis on imaging, FVC greater than or equal to 45% of predicted, and DLCO 30% to less than 80% of predicted. Diagnosis is confirmed by CT with evidence of fibrosis (documenation required).

PA Criteria	Criteria Details
	Reauthorization: Must have documentation from prescriber indicating improvement or stabilization in condition and must provide current FVC and DLCO values.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OGSIVEO

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJEMDA

Products Affected

- OJEMDA ORAL SUSPENSION FOR RECONSTITUTION
- OJEMDA ORAL TABLET 400 MG/WEEK (100 MG X 4), 500 MG/WEEK (100 MG X 5), 600 MG/WEEK (100 MG X 6)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, For suspension: must have chart note documentation of the clinical rationale for why tablets cannot be used.
Age Restrictions	Pediatrics 6 months - 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Low-grade glioma (LGG)-Initial: Approve if the member has relapsed or refractory LGG harboring a BRAF fusion or rearrangment or BRAF V600 mutation as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJJAARA

Products Affected

- OJJAARA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-Initial: Approve if the member has anemia and a diagnosis of intermediate-2 or high-risk disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ONUREG

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member meets both A and B: A) Member achieved first complete remission (CR) or complete remission with incomplete blood count recover (CRi) following intensive induction chemotherapy AND B) Member is not able to complete intensive curative therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPIPZA

Products Affected

- OPIPZA ORAL FILM 10 MG, 2 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Tourette's Disorder-Initial: Approve if the member has a diagnosis of Tourette's Disorder AND provider has submitted clinical rationale why the member cannot use aripiprazole ODT/ solution/tablets. Schizophrenia-Initial: Approve if the member has clinical diagnosis of schizophrenia based on the following criteria: A) two or more of the following present for a significant portion of time during a 1-month period: delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behavior, or negative symptoms. At least one symptom must be delusions, hallucinations, or disorganized speech, B) Continuous signs of disturbance persist for at least 6 months and the disturbance is not attributable to the physiological effects of a substance or another medical condition, and C) Social and/or occupational dysfunction for a significant portion of the time. Clinical rationale why the member cannot use aripiprazole ODT/solution/tablets must be submitted by the provider AND member has tried and failed one other generic formulary antipsychotic or antidepressant used to treat the same indication.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Major Depressive Disorder (MDD)-Initial: Approve if member has diagnosis of MDD based on the following criteria: A) Member has five or more of the following symptoms that have been present during the same two-week period and represent a change from previous functioning (Note: one of the symptoms is either depressed mood or loss of interest or pleasure): 1) depressed mood most of the day, nearly every day, 2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day, 3) significant weight loss when not

PA Criteria	Criteria Details
	dieting or weight gain (e.g. a change of more than 5% in a month), or change in appetite nearly every day, 4) insomnia or hypersomnia nearly every day, 5) psychomotor agitation or retardation nearly every day that are observable by others, 6) fatigue or loss of energy nearly every day, 7) feelings of worthlessness or excessive or inappropriate guilt, 8) diminished ability to think or concentrate, or indecisiveness, nearly every day, 9) recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attemmpt or a specific plan for committing suicide, B) The episode is not attributable to the psysiologoical effects of a substance or to another medical condition (i.e. serious medical illness or disability, financial hardships), AND C) The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders. Clinical rationale why the member cannot use aripiprazole ODT/solution/tablets must be submitted by the provider AND member has tried and failed one other generic formulary antipsychotic or antidepressant used to treat the same indication. Requested medication must be used as adjunctive treatment and not as monotherapy. Reauthorization-All Indications: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ORGOVYX

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Prostate Cancer-Initial: Approve if the member has advanced disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORKAMBI

Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications containing ivacaftor
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a cystic fibrosis specialist
Coverage Duration	12 months
Other Criteria	Initial: Must have a diagnosis of cystic fibrosis and documentation of one of the following: 1) Member is homozygous (two copies) for the F508del mutation in the CFTR gene OR 2) If the member's genotype is unknown, an FDA-cleared cystic fibrosis mutation test used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Provider attestation liver function tests will be assessed prior to initiation of treatement, during the first 6 months of treatment, every 3 months for the next 12 months, then at least annually thereafter. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician, absent of toxicities, and provider attestation to monitor liver function tests at least annually.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORSERDU

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of breast cancer that meets meets the following criteria (A, B, and C): A) Member has advanced or metastatic disease with progression after trying at least one line of endocrine therapy (e.g. fulvestrant, anastrozole, exemestane, letrozole), B) Disease is estrogen receptor positive (ER+) disease, human epidermal growth factor receptor 2 (HER2)-negative disease, estrogen receptor 1 gene (ESR1)-mutated as determined by an FDA-approved test, AND C) Member is a postmenopausal woman or adult male. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OTEZLA

Products Affected

- OTEZLA
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)- 20 MG (51), 10 MG (4)-20 MG (4)-30 MG (47)
- OTEZLA XR
- OTEZLA XR INITIATION

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, targeted synthetic DMARDs, potent immunosuppressants, anti-interleukin monoclonal antibodies, or janus kinase inhibitors.
Required Medical Information	Diagnosis, For all pre-requisite drug trials, members who have already been on biologic therpies not required to step back and try a traditional systemic agent (i.e. conventional systemic DMARDs)
Age Restrictions	Plaque Psoriasis and PsA-6 years and older- All other indications-18 years and older
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: PsA: Dermatologist or rheumatologist. PsO: Dermatologist. Behcets Disease: Dermatologist or rheumatologist
Coverage Duration	12 months
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PANRETIN

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist
Coverage Duration	12 months
Other Criteria	Kaposi Sarcoma (KS)-Initial: Approve if the member will be using the medication for the topical treatment of cutaneous lesions in AIDS-related KS and the provider has confirmed the member does not require systemic treatment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PAZOPANIB

Products Affected

- *pazopanib oral tablet 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Renal Cell Carcinoma (RCC)-Initial: Approve if the member has advanced, relapsed, or unresectable disease with predominant clear cell histology and meets either A or B: A) Medication will be used as first-line therapy as a single agent OR B) Medication will be used as subsequent therapy and as a single agent after disease progression on prior first-line therapy. Soft Tissue Sarcomas (STS)-Initial: Member has a diagnosis of STS other than GIST (e.g. angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or solitary fibrous tumor/hemangiopericytoma or alveolar soft part sarcoma) and the member has progressed after prior chemotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Cholangiocarcinoma-Initial: Approve if the member has unresectable, locally advanced or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test. Member must has been previously treated with at least one systemic therapy regimen prior to approval. Myeloid/Lymphoid Neoplasm (MLN)-Initial: Approve if the member has relapsed or refractory disease. MLN must be documented as fibroblast growth factor receptor 1 (FGFR1) rearrangement as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PENICILLAMINE

Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: Wilson's Disease: Gastroenterologist, hepatologist or liver transplant physician. RA: Rheumatologist. Cystinuria: Nephrologist or inherited metabolic disorders specialist.
Coverage Duration	12 months
Other Criteria	Wilson's Disease-Initial: Approve if member has chart note documentation of how the diagnosis was confirmed including at least one of the following: A) genetic testing indicating biallelic pathogenetic mutation in ATP7B gene OR B) Two of the following clinical features: hepatic parenchymal copper content of at least 250 micrograms per gram dry weight, presence of Kayser-Fleisher Ring in cornea, serum ceruloplasmin level less than 20 mg/dL, or basal 24-hour urinary excretion of copper greater than 100 micrograms (1.6 micromoles). Cystinuria-Initial: Approve if member has chart note documentation of how the diagnosis was confirmed including lab values indicating greater than 500 mg urinary cystine excretion per day. Member must have a trial and failure or contraindication to tiopronin. RA-Initial: Approve if member has severely active disease after a trial and failure of both the following A and B: A) Methotrexate tablets or injection AND B) A preferred biologic therapy (e.g. a preferred adalimumab product, a preferred ustekinmab product, Rinvoq, Skyrizi, Otezla, or Xeljanx/XR). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PHENYLBUTYRATE

Products Affected

- *sodium phenylbutyrate*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of any other phenylbutyrate product
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a provider who specializes in the treatment of inherited metabolic disorders
Coverage Duration	12 months
Other Criteria	Initial: Member must have diagnosis of urea cycle disorder confirmed by either A or B: A) Member had a genetic test confirm a mutation resulting in a urea cycle disorder (test result requred) OR B) hyperammonemia with ammonia levels above the upper limit of normal (test result with reference range required). Member must have disease that cannot be managed by protein restriction or amino acid supplemenation alone. Medication will be used in combination with dietary protein restriction. Reauthorization: Approve if documenation from provider indicates improvement in condition based on decreased ammonia levels while on therapy and medication will continue to be used in combination with a protein restricted diet.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PIMECROLIMUS (TOPICAL)

Products Affected

- *pimecrolimus*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of atopic dermatitis. Member must have a trial and failure or contraindication to a moderate to high potency topical corticosteroid (Note: Potency exceptions may be made for members with dermatitis affecting the face or intertriginous areas) and topical tacrolimus ointment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PIQRAY

Products Affected

- PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 300 MG/DAY (150 MG X 2)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Initial: Approve if the member has advanced or metastatic disease meets the following criteria (A, B, and C): A) Disease is hormone receptor (HR)-positive, has human epidermal growth factor receptor 2 (HER2)-negative, and PIK3CA-mutated breast cancer as detected by an FDA-approved test, B) Disease has progressed on or after an endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene) AND C) Medication will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PIRFENIDONE

Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 801 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	Idiopathic Pulmonary Fibrosis (IPF)-Initial: Member must have FVC greater than or equal to 40% of the predicted value. Must have diffusing capacity for carbon monoxide (DLCO) 30% to 90% of predicted. IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP with all other diagnoses ruled out (e.g. domestic and occupational enviornmental exposures, connective tissue disease, and drug toxicity). Reauthorization: Must have documentation from prescriber indicating improvement or stabilization in condition and must provide current FVC and DLCO values.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PLEGRIDY

Products Affected

- PLEGRIDY INTRAMUSCULAR
- PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML
- PLEGRIDY SUBCUTANEOUS SYRINGE 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of relapsing forms of multiple sclerosis (RRMS). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Kaposi Sarcoma-Initial: Approve if the member meets one of the following (i or ii): i. Member is Human Immunodeficiency Virus (HIV)-negative OR ii. Member meets both of the following (A and B): A) Member is Human Immunodeficiency Virus (HIV)-positive AND B) Member failed highly active antiretroviral therapy (HAART). Multiple Myeloma (MM)-Initial: Approve if the member meets the following criteria A and B: A) Member will receive the medication in combination with dexamethasone, B) Member has received at least two prior therapies including lenalidomide (Revlimid) and a proteasome inhibitor, AND C) Member has demonstrated disease progression on or within 60 days of completion of the last therapy. For all diagnoses, member must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and member must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

POSACONAZOLE (ORAL)

Products Affected

- *posaconazole oral tablet,delayed release (dr/ec)*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with CYP3A4 substrates that prolong the QT interval (e.g., pimozide, quinidine), sirolimus, HMG-CoA reductase inhibitors that are primarily metabolized through CYP3A4 (e.g., atorvastatin, lovastatin, simvastatin), ergot alkaloids, venetoclax at initiation and during the ramp-up phase in patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Prophylaxis-Initial: Member must be using medication as prophylaxis against invasive aspergillus and candida infections. Member must be severely immunocompromised (i.e. hematopoietic stem cell transplant [HSCT], recipient with graft vs host disease [GvHD], or members with prolonged neutropenic from chemotherapy for hematologic malignancies such as acute myelogenous leukemia [AML] or myelodysplastic syndromes [MDS]). Reauthorization: Members requiring further treatment will be reassessed using the initial criteria.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PRETOMANID

Products Affected

- PRETOMANID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease physician or a pulmonologist
Coverage Duration	6 months
Other Criteria	Initial: Approve if the member has diagnosis of pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis that is resistant to at least rifampin and isoniazid. Medication will not be used to treat latent, extra-pulmonary or drug-sensitive TB or for the treatment of infections caused by non-tuberculous mycobacteria. Medication will not be used to treat tuberculosis that is resistant to isoniazid and rifampin when responsive to standard therapy and NOT treatment-intolerant. Requested medication must be prescribed as part of a combination known as BPaL regimen or BPaLM regimen, including bedaquiline, pretomanid, and linezolid, with or without moxifloxacin. Reauthorization: If a member requires treatment beyond the recommended timeframe, documentation from prescriber indicating the member's initial response to therapy and clinical rationale for continuation of treatment or for re-treatment must be provided. Chart note documenation of susceptibility testing of Mycobacterium tuberculosis isolates demonstrating continued susceptibility to the requested medication is required.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

PREVYMIS

Products Affected

- PREVYMIS ORAL PELLETS IN PACKET
- PREVYMIS ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with pimozide and/or ergot alkaloids or with pitavastatin and simvastatin when co-administered with cyclosporine
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a hematologist, infectious disease physician, oncologist, or transplant physician
Coverage Duration	210 days
Other Criteria	Prophylaxis of Cytomegalovirus (CMV)-Initial: Approve if the member is using the requested medication as prophylaxis of CMV infection and disease and the member meets either A or B: A) Member weighs at least 6 kg and is a CMV-seropositive recipient [R+] of an allogenic hematopoietic stem cell transplant (HSCT). Member must have received an allogeneic hematopoietic stem cell transplant. Medication will be initiated within 28 days post-transplant OR B) Member weighs at least 40 kg and is a kidney transplant recipient at high risk where the donor is CMV seropositive and the recipient is CMV seronegative (D+/R-). Member must have a medical reason as to why valganciclovir therapy cannot be started or continued (e.g., breakthrough CMV infection, adverse effects leading to discontinuation of valganciclovir). For all diagnoses, treatment duration must not exceed 200 days post-transplant. Reauthorization: Members requiring further treatment will be reassessed using the initial criteria.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

PROLIA

Products Affected

- JUBBONTI
- STOBOCLO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Osteoporosis-Initial: Approve if used to treat osteoporosis in a member that is a post-menopausal female or male (Note: female and male are defined as an individual with the biological traits of a female or male, regardless of the individual's gender identity or gender expression) AND member meets one of the following A, B, C, or D: A) Member has had inadequate response after 6 months of therapy with an oral bisphosphonate, had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, B) Member cannot take an oral bisphosphonate because they cannot swallow or have difficulty swallowing, they cannot remain in an upright position, or they have a pre-existing GI medical condition, C) Member has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR D) Member has severe renal impairment (e.g., CrCl less than 35 mL/min) or CKD, or if the member has an osteoporotic fracture or fragility fracture . Androgen Deprivation Therapy (ADT) Bone Loss-Initial: Approve if member is receiving ADT (e.g., leuprolide, triptorelin, goserelin) for non-metastatic prostate cancer and at high risk for fracture or the patient has undergone a bilateral orchiectomy. Aromatase Inhibitor (AI) Bone Loss-Initial: Approve if member is receiving adjuvant AI therapy (e.g., anastrozole, letrozole, exemestane) for breast cancer and at high risk for fracture. Glucocorticoid-Induced Osteoporosis (GIO)-Initial: Approve if member meets either A, B, C, or D: A) Member tried and failed or has a contraindication (i.e., unable

PA Criteria	Criteria Details
	to swallow, difficulty swallowing, inability to remain upright post-administration, pre-existing GI medical condition [e.g., esophageal lesions or ulcers, abnormalties that delay esophageal emptying] one oral bisphosphonate, B) Member has tried zoledronic acid (Reclast), C) Member has severe renal impairment (e.g., CrCl less than 35 mL/min) or CKD, OR D) Member has an osteoporotic fracture or fragility fracture. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PROMACTA

Products Affected

- *eltrombopag olamine oral powder in packet 12.5 mg, 25 mg*
- *eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Myelodysplastic Syndrome (MDS)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	ITP, Aplastic Anemia: Prescribed by or in consultation with a hematologist or oncologist. Hepatitis C: Prescribed by or in consultation with a gastroenterologist, hematologist, hepatologist, or infectious disease specialist.
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other Criteria	First-Line Severe Aplastic Anemia (SAA)-Initial: Approve if member has diagnosis of SAA as evidenced by TWO of the following i, ii, iii: i) Absolute neutrophil count (ANC) less than 0.5 x 109/L, ii) Platelet count is less than 20 x 109/L, iii) Reticulocyte count less than 1% corrected or less than 60 x 109/L AND must submit documentation confirming platelet levels are less than 50 x 109/L AND medication must be used in combination with standard immunosuppressive therapy (e.g. cyclosporine, antithymocyte immune globulin). Refractory Severe Aplastic Anemia (SAA)-Initial: Approve if member has diagnosis of SAA as evidenced by TWO of the following i, ii, iii: i) Absolute neutrophil count (ANC) less than 0.5 x 109/L, ii) Platelet count is less than 20 x 109/L, iii) Reticulocyte count less than 1% corrected or less than 60 x 109/L AND must submit documentation confirming platelet levels are less than 50 x 109/L AND member must have a trial with an inadequate response or significant side effect to immunosuppressive therapy (e.g. cyclosporine, antithymocyte, cyclophosphamide). Chronic Hepatitis C Infection-Associated Thrombocytopenia-Initial: Approve if member has diagnosis AND documentation submitted confirming platelet levels are less than 75 x 109/L. Provider attests requested medication will be used to achieve the

PA Criteria	Criteria Details
	target platelet count necessary to initiate antiviral therapy and to avoid reductions in concomitant interferon-based therapy. Persistent or Chronic Immune Thrombocytopenia (ITP)-Initial: Approve if member has diagnosis of ITP AND has had an insufficient response to corticosteroids (i.e. 0.5-2.0 mg/kg prednisone per day), immunoglobulins (IVIG), or splenectomy. Provider must attest the degree of thrombocytopenia and clinical condition increases the risk for bleeding. Reauthorization-All Other Indications: Approve if platelet count meets one of the following i, ii, iii: i) less than 50 x 109/L, ii) greater than or equal to 50 x 109/L to 200 x 109/L, iii) greater than or equal to 200 x 109/L to less than or equal to 400 x 109/L with an adjustment to reduce daily dose AND provider attests to regularly monitoring liver function and hematology laboratory tests. Provider attests member is not experiencing any signs or symptoms of hepatic injury or thromboembolism AND the requested medication will not be used in combination with another thrombopoietin receptor agonist or with Tavalisse (fostamatinib). Members with Chronic Hepatitis C induced thrombocytopenia must continue to receive interfereon-based therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PULMOZYME

Products Affected

- PULMOZYME

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cystic fibrosis specialist or pulmonologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of cystic fibrosis. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Note: B versus D determination will me made prior to application of clinical criteria
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PYRIMETHAMINE

Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious diseases specialist
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Gastrointestinal Stromal Tumor (GIST)-Initial: Approve if the member has a diagnosis of advanced GIST and has received prior treatment with imatinib AND two or more other kinase inhibitors (e.g. sunitinib, dasatinib). Medication will be used as monotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

QULIPTA

Products Affected

- QULIPTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Episodic Migraine Prevention-Initial: Approve if the member has a diagnosis of episodic migraine with or without aura based upon ICHD-3 criteria: Member has headaches occuring on greater than or equal to 4 but less than 15 days/month and meets the following A, B, or C: A) Member had five or more lifetime attacks, B) Headaches meet at least two of the four characteristics: unilateral location, pulsating quality, moderate or severe pain intensity, aggravation by or causing avoidance of routine physical activity (e.g., walking or climbin stairs) AND C) at least one of the following occurred during the headache: nausea and/or vomiting, photophobia and/or phonophobia. Provider attests the diagnosis is not better accounted for by another ICHD-3 diagnosis (i.e. medication overuse) and medication will not be used concomitantly with onabotulinumtoxin A (Botox). Chronic Migraine Prevention-Initial: Approve if the member has a diagnosis of chronic migraine with or without aura based upon ICHD-3 criteria: Member has migraine-like or tension-type headaches occuring on 15 or more days/month for more than 3 months and on at least 8 days per month for greater than 3 months, fulfills any of the following A, B, or C: A) Members having migraine without aura has headaches with at least two of the four characteristics: unilateral location, pulsating quality, moderate or severe pain intensity, aggravation by or causing avoidance of routine physical activity (e.g., walking or climbin stairs) AND at least one of the following occurred during the headache: nausea and/or vomiting,

PA Criteria	Criteria Details
	photophobia and/or phonophobia, B) Members having migraine with aura has headaches with one or more of the following fully reversible aura symptoms: visual, sensory, speech and/or language, motor brainstem, retinal AND at least three of the following six characteristics: at least one aura symptom spreads gradually over greater than or equal to 5 minutes, two or more aura symptoms occur in succession, each individual aura symptom lasts 5-60 minutes, at least one aura symptom is unilateral, at least one aura symptom is positive, the aura is accompanied, or followed within 60 minutes by headache, or C) believed by the member to be migraine at onset and relieved by a triptan or ergot derivative. Provider attests the diagnosis is not better accounted for by another ICHD-3 diagnosis (i.e. medication overuse) and medication will not be used concomitantly with onabotulinumtoxin A (Botox). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

RALDESY

Products Affected

- RALDESY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if member has a diagnosis of Major Depressive Disorder based on the following: A) Member has five or more of the following symptoms that have been present during the same two-week period and represent a change from previous functioning (Note: one of the symptoms is either depressed mood or loss of interest or pleasure): 1) depressed mood most of the day, nearly every day, 2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day, 3) significant weight loss when not dieting or weight gain (e.g. a change of more than 5% in a month), or change in appetite nearly every day, 4) insomnia or hypersomnia nearly every day, 5) psychomotor agitation or retardation nearly every day that are observable by others, 6) fatigue or loss of energy nearly every day, 7) feelings of worthlessness or excessive or inappropriate guilt, 8) diminished ability to think or concentrate, or indecisiveness, nearly every day, 9) recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attemmpt or a specific plan for committing suicide, B) The episode is not attributable to the psysiologoical effects of a substance or to another medical condition (i.e. serious medical illness or disability, financial hardships), AND C) The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders. The member must have a trial and failure of two generic

PA Criteria	Criteria Details
	antidepressants used to treat the same indication prior to approval (i.e. sertraline concentrate, fluoxetine solution, citalopram solution, escitalopram solution). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REPATHA

Products Affected

- REPATHA
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of with other injectable lipid lowering medications
Required Medical Information	Diagnosis
Age Restrictions	ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	12 months
Other Criteria	NOTE: Statin intolerance is statin related rhabdomyolysis or skeletal-related muscle sx while receiving separate trials of atorvastatin and rosuvastatin and during both trials the sx resolved upon dc. High intensity statin: Atorvastatin at least 40 mg daily or Rosuvastatin at least 20 mg daily). HeFH-approve if pt has untreated LDL-C greater than or equal to 190 mg/dL (160 mg/dL for members less than 20 yrs) AND pt tried ONE high intensity statin (defined above) with inadequate results, unless statin intolerant (defined above). ASCVD Hyperlidemia-approve if pt has hx of either: CAD, MI, ACS, CVA or TIA, PAD, dx of angina, undergone coronary or other arterial revascularization procedure) AND tried ONE high intensity statin and LDL remains 55 mg/dL or higher unless, statin intolerant (defined above). HoFH-approve if pt tried ONE high intensity statin for at least 8 weeks with inadequate results, unless statin intolerant (defined above) AND pt meets ONE: A) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR B) untreated LDL greater than 400 mg/dL (prior to treatment) AND has clinical manifestations of HoFH before the age of 20 (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma) OR C) untreated elevated LDL-C levels consistent with HeFH in both parents (Note: In digenic form, one parent may have normal

PA Criteria	Criteria Details
	LDL-C levels and the other may have LDL-C levels consistent with HoFH). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the pt has tried one high-intensity statin, unless statin intolerant (defined above) and ezetimibe for 8 weeks or longer and LDL remains 55 mg/dL or higher OR has baseline LDL-C 190 or greater prior to tx with therapy. MACE Reduction in members without established CVD-Approve if pt is at an increased risk for CV events (i.e., MI, stroke, etc) AND has tried one high-intensity statin therapy, unless statin intolerant (defined above) AND ezetimibe for 8 weeks or longer and LDL remains 55 mg/dL or higher.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RETEVMO

Products Affected

- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors with RET gene fusion: 2 years and older, NSCLC: 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has locally advanced or metastatic disease AND the tumor is RET fusion-positive as detected by an FDA-approved test. Medullary Thyroid Cancer-Initial: Approve if the member has advanced or metastatic RET-mutant disease as detected by an FDA-approved test AND the disease requires treatment with systemic therapy. RET Fusion-Thyroid Cancer-Initial: Approve if the member has advanced or metastatic thyroid cancer with a RET gene fusion as detected by an FDA-approved test. Member requires systemic therapy and is radioactive iodine-refractory (if radioactive iodine is appropriate). RET Fusion-Positive Solid Tumors-Initial: Approve if member has locally advanced or metastatic solid tumors with a RET gene fusion as detected by an FDA-approved test that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVCOVI

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, hematologist or oncologist
Coverage Duration	12 months
Other Criteria	Approve if the member has Severe Combined Immunodeficiency Disease (SCID) with a definitive diagnosis of Adenosine Deaminase Deficiency as determined by one of the following A or B: A) Deficient ADA catalytic activity (less than 1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts) OR B) Detection of pathogenic mutations in the ADA gene by molecular genetic testing. Member must have a marked elevation of the metabolite dATP or total dAdo nucleotides (the sum of dAMP, dADP and dATP) in erythrocytes. Reauthorization: Approve if the member has responded positively to therapy with stabilization in condition as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVUFORJ

Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member's disease is relapsed or refractory and meets either A or B: A) Member has a diagnosis of acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation as detected by an FDA-approved test OR B) Member has a diagnosis of Acute Myeloid Leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation as determined by an approved test AND member has no satisfactory alternative treatment options. Reauthorization: Member has responded positively to therapy as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZDIFFRA

Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of non-alcoholic steatohepatitis or metabolic dysfunction associated steatohepatitis (NASH/MASH). Member must have at least one of the following cardeometabolic risk factors: BMI at least 25 kg/m2, hypertension, dyslipidemia, prediabeties, or type 2 diabetes. Member must have steatosis on imagining (e.g., ultrasound, Fibroscan CAP, MRI-PDFF) or liver biopsy (documentation required). Member must have moderate to advanced liver fibrosis confirmed by one of the following performed in the last 6 months: 1) Liver biopsy shows fibrosis stage F2 or F3 AND a non-alcoholic fatty liver disease activity score (NAS) of at least 4 with a score of greater than 1 in all the following: steatosis, ballooning, and lobular inflammation OR 2) Test results from the previous 6 months documenting liver fibrosis stage F2 to F3 OR FIB-4 greater than or equal to 1.3 AND one of the following non-invasive tests consistent with F2 to F3 fibrosis (documentation required): transient elastography (FibroScan), magnetic resonance elastography (MRE), or shear wave elastography. Must not have evidence of cirrhosis (stage 4 fibrosis) by imaging or liver biopsy or one or more liver-related complications associated with cirrhosis (i.e. variceal bleeding, ascites, hepatic encephalopathy). Provider must attest member does not have significant alcohol use (defined as alcohol consumption of more than 1 drink per day for natal females or more than 2 drinks per day for natal males). Requested medication will be used in combination with appropriate

PA Criteria	Criteria Details
	diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise). Reauthorization: Approve if the member has chart note documentation of all the following: improvement or stabilization in condition, no evidence of cirrhosis (stage F4 fibrosis) by imaging or liver biopsy or one or more liver-related complications associated with cirrhosis (e.g., variceal bleeding, ascites, hepatic encephalopathy, etc.). Must have attestation from prescriber that the member does not have significant alcohol use (defined as alcohol consumption of more than 1 drink/day for natal females or more than 2 drinks/day for natal males), and must continue to be used in conjunction with diet and exercise.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZLIDHIA

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member has relapsed or refractory disease with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, or transplant specialist
Coverage Duration	12 months
Other Criteria	Chronic Graft versus Host Disease (cGVHD)- Initial: Approve if the member has a diagnosis of cGVHD and has tried two or more conventional systemic treatments for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus). Reauthorization: Must have documentation from the provider that the condition has improved based upon the prescriber assessment while on therapy or the member continues to benefit from therapy. Requests for doses that exceed 200mg daily must meet both A and B: A) Documentation of a drug interaction with either a proton pump inhibitor (e.g., omeprazole, pantoprazole) or strong CYP3A inducer (e.g. rifampin, phenytoin, carbamazepine) AND B) Attestation from the provider that continued treatment with the interacting medication in combination with belumosudil (Rezurock) is medically necessary.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

RILUZOLE

Products Affected

- *riluzole*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS
Coverage Duration	12 months
Other Criteria	Initial: Approve if according to the prescribing physician, the member has a definite or probably diagnosis of amyotrophic lateral sclerois (ALS), based on the application of the El Escorial or the revised Airlie house diagnostic criteria. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

RINVOQ

Products Affected

- RINVOQ ORAL TABLET EXTENDED RELEASE 24 HR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, targeted synthetic DMARDs, potent immunosuppressants, anti-interleukin monoclonal antibodies, or janus kinase inhibitors.
Required Medical Information	Diagnosis, For all pre-requisite drug trials, members who have already been on biologic therpies not required to step back and try a traditional systemic agent.
Age Restrictions	RA/UC/CD/AS/nr-axSpA/GCA: 18 years and older
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: RA/AS/nr-axSpA/PJIA/GCA-Rheumatologist. PsA-Rheumatologist or dermatologist. AD-Allergist, immunologist or dermatologist. UC/CD-Gastroenterologist
Coverage Duration	12 months
Other Criteria	Psoriatic Arthritis(PsA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following (documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Member must have a trial and failure or contraindication to a tumor necrosis factor inhibitor (TNFi). Atopic Dermatitis (AD)-Initial: Approve if the member has refractory, moderate to severe disease and had a trial and failure or a contraindication to a 3-month trial of at least one systemic therapy (i.e. csDMARD, bDMARD). Ulcerative Colitis (UC)/Crohn's Disease (CD)-Initial: Approve if the member has moderately to severely active disease and has had a trial and failure or contraindication to a TNFi, unless clinically unadvisable. If TNF blockers are clinically unadvisable, member should have received at least one approved systemic therapy previously. Rheumatoid Arthritis (RA)-Initial: Approve if the member has moderately to severely active disease and has had a trial and failure or contraindication to a TNFi. Ankylosing Spondylitis (AS)-Initial: Approve if the member has active disease and has had a trial and failure or

PA Criteria	Criteria Details
	contraindication to a TNFi. Non-Radiographic Axial Spondyloarthritis (nr-axSpA)-Initial: Approve if the member has objective signs of inflammation defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI. Member must have had a trial and failure or a contraindication to a TNFi. Polyarticular Juvenile Idiopathic Arthritis (PJIA)-Approve if member has had a trial and failure or a contraindication to a TNFi. Giant Cell Arteritis (GCA)-Initial: Approve if documentation of temporal artery biopsy confirming diagnosis (biopsy result required) and member has received high-dose glucocorticoids (i.e. prednisone 40mg - 60mg, or maximally tolerated dose), unless member has contraindication to the use of glucocorticoids. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ROFLUMILAST

Products Affected

- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	Moderate to severe liver impairment (Child-Pugh B or C)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Obstructive Pulmonary Disease (COPD)-Initial: Approve if member has a diagnosis of severe COPD and meets the following: A) Patient has a history of exacerbations, B) Member has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone), C) Member will be titrated to maintenance dose of 500 mcg after 4 weeks of therapy, and D) Member will continue maintenance medication with LABA or LAMA for duration of therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and member will continue maintenance medication with LABA or LAMA for duration of therapy
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ROMVINZA

Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if member has a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) where surgical resection will potentially cause worsening functional limitation or severe morbidity. Provider must attest liver function tests will be evaluation prior to initiation of treatment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and provider attests liver function tests will continue to be monitored during treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROZLYTREK

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PELLETS IN PACKET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Solid Tumors-Initial: Approve if the member meets the following (A, B, and C): A) The member has metastatic tumors or surgical resection is likely to result in severe morbidity, B) Tumors have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion as detected by an FDA-approved test without a known acquired resistance mutation, AND C) Disease has progressed on prior therapies or there are no acceptable alternative therapies. Non-Small Cell Lung Cancer-Initial: Approve if member has ROS1-positive metastatic disease as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-Initial: Approve if the member will be using the requested medication for maintenance therapy. The member's disease is recurrent, metastatic, and positive for a deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test. Member had complete or partial response to platinum-based chemotherapy. Medication will be used as monotherapy. Prostate Cancer-Initial: Approve if the member's disease is metastic and castration-resistant prostate cancer (mCRPC) and member meets the following (A, B, and C): A) Disease is positive for a deleterious BRCA mutation (germline or somatic) as detected by an FDA-approved test, B) Member has been treated with androgen receptor-directed therapy (e.g. abiraterone, apalutamide [Erleada]) and a taxane-based chemotherapy (e.g. docetaxel), AND C) Medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR member has had a bilateral orchiectomy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RUFINAMIDE

Products Affected

- *rufinamide oral suspension*
- *rufinamide oral tablet 200 mg, 400 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, For suspension, must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of Lennox-Gastaut Syndrome (LGS) and meets the following (A and B): A) Requested medication will be used as adjunctive treatment to other antiepileptic drugs, AND B) Member had a trial and failure or contraindication to two generic antiepileptic drugs (e.g. lamotrigine, topiramate). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member has a diagnosis of AML that is newly diagnosed and meets the following (A and B): A) Disease is FLT3 mutation-positive as detected by an FDA-approved test AND, B) Medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), or Mast Cell Leukemia-Initial: Approve. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SANDOSTATIN LAR

Products Affected

- *octreotide,microspheres*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments/therapies
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. All neuroendocrine tumors-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist or neurosurgeon. Merkel cell/Thymoma/Thymic carcinoma-prescr/consult w/oncologist. Diarrhea assoc w chemo-presc/consult oncologist/gastro.
Coverage Duration	Enterocutaneous fistula/diarrhea assoc w chemo - 3 months, all others - 1 year
Other Criteria	Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Diarrhea assoc w chemo (A and B): A) grade 3 or 4 diarrhea and B) patient has tried at least one antimotility medication. Merkel cell carcinoma (A and B): A) patient has regional or distant metastatic disease and B) has contraindications to or has progressed on checkpoint immunotherapy. Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas)-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma, enterocutaneous fistulas, diarrhea associated with chemotherapy, Merkel cell carcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

SAPROPTERIN

Products Affected

- *sapropterin*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Pegvaliase-pqpz (Palynziq)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	Initial: 3 months Reauthorization: 12 months
Other Criteria	Initial: Approve if member has hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive phenylketonuria (PKU. Provider must send chart note documentation of baseline blood phenylalanine showing a level greater than 360 micromol/L. Must provide current weight and requested dose must fall within recommended dosing guidelines from the manufacturer. Member will be using requested medication in conjunction with a Phe-restricted diet, including dietary protein and Phe restriction. Reauthorization: Approve if the member has responded positively to therapy as evidenced by a decrease in blood phenylalanine level from baseline. If member has not had a decrease in blood phenylalanine level, must have documentation of dose increase to 20 mg/kg/day. Authorizations for these members are extended for an additional one month trial at the higher dose. Authorizations for members who have not had a decrease in blood phenylalanine level at the 20 mg/kg/day dose may not be extended. Member will continue using requested medication in conjunction with a Phe-restricted diet, including dietary protein and Phe restriction
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

SCEMBLIX

Products Affected

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Myeloid Leukemia (CML)-Initial: Approve if the member meets either of the following (A, B, or C): A) Member has newly diagnosed Philadelphia chromosome-positive (Ph+) CML as detected by an FDA-approved test and member is in chronic phase, B) Member has Ph+ CML as detected by an FDA-approved test that has been previously treated and is in chronic phase, OR C) Member has Ph+ CML that is T315I-positive as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	Severe Hepatic impairment (Child-Pugh C)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's Disease
Coverage Duration	12 months
Other Criteria	Cushing's Disease-Initial: Member must have diagnosis of Cushing's Disease and meet the following (A, B, C, and D): A) Previously had pituitary surgery (e.g., transsphenoidal surgery) that was not curative or must not be a candidate for surgery, B) Must provide a baseline 24-hour urinary free cortisol level, C) Must have recent (within 6 months) baseline assessment of hemoglobin A1C and provide documentation of anti-diabetic therapy if baseline hemoglobin is greater than 8%, AND D) Documention showing confirmation that the source of Cushing's Disease is pituitary. Reauthorization: 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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SILDENAFIL (PAH)

Products Affected

- *sildenafil (pulmonary arterial hypertension) oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of nitrate products or guanylate cyclase (GC) stimulators
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	Initial: Member must have a diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Must have chart note documentation of a right-heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than 20 mmHg, pulmonary capillary wedge pressure or left atrial pressure or left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than or equal to 3 wood units. Member must have WHO Functional Class II-IV symptoms. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease physician or a pulmonologist
Coverage Duration	6 months
Other Criteria	Initial: Approve if the member has diagnosis of pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis that is resistant to at least rifampin and isoniazid. Medication will not be used to treat latent, extra-pulmonary or drug-sensitive TB or for the treatment of infections caused by non-tuberculous mycobacteria. Must meet either A or B: A) Requested medication will be prescribed as part of a combination regimen with at least three other anti-tuberculosis agents the member's TB isolate has shown to be susceptible to in vitro OR if in vitro testing results are unavailable, the requested medication will be used in combination with at least 4 other drugs to which the member's TB isolate is likely to be susceptible OR B) Requested medication will be prescribed as part of a combination regimen known as BPaL that includes the use of the requested medication, pretomanid, and linezolid . Reauthorization: If a member requires treatment beyond the recommended timeframe, documentation from prescriber indicating the member's initial response to therapy and clinical rationale for continuation of treatment or for re-treatment must be provided. Chart note documenation of susceptibility testing of Mycobacterium tuberculosis isolates demonstrating continued susceptibility to the requested medication is required.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SKYRIZI

Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360 MG/2.4 ML (150 MG/ML)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-presc/consult-gastro
Coverage Duration	12 months
Other Criteria	Note: Members must have induction within the previous 3 months prior to initiating therapy with Skyrizi subcutaneously. Plaque Psoriasis (PsO)-Initial: Approve if the member has chronic moderate to severe disease and member has tried and failed or has a contraindication to at least one systemic therapy for 3 months with inadequate results (i.e. phototherapy, methotrexate, acitretin). Psoriatic Arthritis (PsA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following (documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Crohns Disease-Initial: Approve if the member has moderate-to-severe disease based on evidence of large or deep ulcers, strictures, or extensive areas of disease and/or evidence of stricturing, penetrating, or perianal disease on endoscopy. Ulcerative Colitis (UC)-Initial: Approve if the member has moderate-to-severe disease based on the following: A) Member presents with frequent, bloody stools that occur 6 or more times daily or frequent and heavy rectal bleeding AND B) Member has severe inflammation or ulcers as visualized on endoscopy. Reauthorization:

PA Criteria	Criteria Details
	Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SODIUM OXYBATE

Products Affected

- SODIUM OXYBATE

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with sedative hypnotics or alcohol. Succinic semialdehyde dehydrogenase deficiency.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a board certified sleep specialist or neurologist
Coverage Duration	12 months
Other Criteria	Excessive daytime sleepiness (EDS)-Initial: Approve for members with a diagnosis of EDS in members with narcolepsy where the member has tried and failed at least one central nervous system (CNS) stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil (for members 18 years of age and older only). Member must have chart note documentation of a history of excessive daytime sleepiness. Narcolepsy must been confirmed with polysomnography and a multiple sleep latency test (MSLT) with documentation submitted. Cataplexy-Initial: Approve for members using the requested medication for cataplexy treatment in members with narcolepsy when the diagnosis has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Documentation of both is required prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

SOLTAMOX

Products Affected

- SOLTAMOX

PA Criteria	Criteria Details
Exclusion Criteria	Members who require concomitant warfarin therapy or have a history of deep vein thrombosis or pulmonary embolus, if the indication for treatment is either reduction of breast cancer incidence in high-risk patients or risk reduction of invasive breast cancer after treatment of DCIS.
Required Medical Information	Diagnosis and must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	Acromegaly-Initial: Approve if the member has a confirmed diagnosis of acromegaly with the following baseline labs (test result with reference range required): elevated serum IGF-1 level for gender/age OR an elevated growth hormone level defined as GH at least 1ng/mL during oral glucost tolerance test. Member must have inadequate response to surgery or documentation that this therapy is inappropriate. Trial and failure or contraindication to a dopamine agonist (i.e. bromocriptine) or somatostatin analogue (i.e. octreotide) prior to approval is required. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SORAFENIB

Products Affected

- *sorafenib*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with carboplatin and paclitaxil in members with squamous cell lung cancer
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Hepatocellular Carcinoma-Initial: Approve if disease is unresectable. Renal Cell Carcinoma-Initial: Approve if disease is advanced after member has tried at least one systemic therapy. Differentiated Thyroid Carcinoma (DTC): Approve if disease is locally recurrent, metastatic, or progressive and refractory to iodine treatment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SPRITAM

Products Affected

- SPRITAM ORAL TABLET FOR SUSPENSION 1,000 MG, 250 MG, 500 MG, 750 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, Must have chart documentation of the clinical rationale for why levetiracetam oral tablet and oral solution cannot be used.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of seizures. Member had a trial and failure or contraindication ot two generic antiepileptic drugs and meets either A, B, or C: A) Member has partial-onset seizures and weighs more than 20 kg, B) Member has myoclonic seizures and will be using medication as adjunctive therapy , OR C) Member has primary generalized tonic-clonic seizures and will be using the requested medication as adjunctive therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and will continue to use the medication as adjunctive therapy if treating myoclonic or generalized tonic-clonic seizures.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Gastrointestinal Stromal Tumor (GIST)-Initial: Approve if the member has a diagnosis of locally advanced, unresectable or metastatic GIST after treatment with imatinib mesylate AND sunitinib malate (Sutent). Hepatocellular Carcinoma (HCC)-Initial: Approve if the member has a diagnosis of HCC and has been previously treated with sorafenib (Nexavar). Metastatic Colorectal Cancer (mCRC)-Initial: Approve if the member has a diagnosis of mCRC and has been previously treated with all the following: A)fluoropyrimidine- (e.g., 5-fluorouracil, capecitabine), oxaliplatin-, and irinotecan-based chemotherapy, B) an anti-VEGF therapy (e.g. bevacizumab), AND C) if member has RAS wild-type (i.e. KRAS and NRAS mutation negative) and medically appropriate, an anti-EGFR therapy (e.g. cetuximab (Erbitux), panitumumab (Vectibix). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

STRENSIQ

Products Affected

- STRENSIQ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	Disease onset-less than or equal to 18
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders.
Coverage Duration	1 year
Other Criteria	Hypophosphatasia - Perinatal/Infantile- and Juvenile-Onset-Patient must meet both A and B for approval. A) Diagnosis is supported by one of the following (i, ii, or iii): i. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation OR ii. Low baseline serum alkaline phosphatase activity OR iii. An elevated level of a tissue non-specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'-phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND B) Patient meets one of the following (i or ii): i. Patient currently has, or has a history of clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, Vitamin B6-dependent seizures) OR ii. Patient has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

SUCRAID

Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	Hypersensitivity to yeast, yeast products, glycerin (glycerol) or papain
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID) and meets both A and B: A) Diagnosis of CSID is established by one of the following (i or ii): i) Member has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by all the following (a, b, c, and d) (test result with reference ranges must be provided): a) Decreased (usually absent) sucrase levels, b) Decreased or normal isomaltase (palatinase), c) Decreased maltase, and d) Decreased or normal lactase OR ii) Member has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely patogenic sucrase-isomaltase gene variant, AND B) Member has symptomatic congenital sucrose-isomaltase deficiency (e.g. diarrhea, bloating, abdominal cramping). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

SUNITINIB

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Gastrointestinal Stromal Tumors (GIST)-Initial: Approve if the member has a diagnosis of GIST and had disease progression on or intolerance to imatinib mesylate. Renal Cell Carcinoma (RCC)-Initial: Approve if the member meets A or B: A) Member has advanced disease OR B) Member is at high risk of recurrent RCC following nephrectomy and will be using the requested medication as adjuvant therapy. Pancreatic Neuroendocrine Tumors (pNET)-Initial: Approve if the member has unresectable locally advanced or metastatic disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SYNAREL

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Endometriosis: 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Central Precocious Puberty: 12 months, Endometriosis: 6 months
Other Criteria	Central Precocious Puberty (CPP)-Initial: Approve. Endometriosis-Initial: Approve if the member has tried one of the following, unless contraindicated, a contraceptive, an oral progesterone or a depo-medroxyprogesterone injection. Note: An exception to the requirement for a trial of the above therapies can be made if the member has previously used a gonadotropin-releasing hormone (GnRH) agonist or antagonist for endometriosis. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TABLOID

Products Affected

- TABLOID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 months
Other Criteria	Approve if requested medication will be used for the remission induction and remission consolidation treatment of acute nonlymphocytic leukemias. Provider must attest medication will not be used during maintenance therapy or similar long term continuous treatments due to the high risk of liver toxicity.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease with tumors positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TACROLIMUS (TOPICAL)

Products Affected

- *tacrolimus topical*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of atopic dermatitis. Member must have a trial and failure or contraindication to a topical corticosteroid. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TADALAFIL (BPH)

Products Affected

- *tadalafil oral tablet 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Use for erectile dysfunction (ED) without the signs and symptoms of benign prostatic hyperplasia (BPH). Concomitant use of nitrate products or guanylate cyclase (GC) stimulators.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of benign prostatic hyperlasia (BPH) and had a trial and failure or documented contraindication to an alpha blocker (e.g. tamsulosin, alfuzosin) and a 5-alpha reductase inhibitor (e.g. finasteride, dutasteride). Medication will be dosed once daily. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TADALAFIL (PAH)

Products Affected

- *tadalafil (pulmonary arterial hypertension) oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of nitrate products or guanylate cyclase (GC) stimulators
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	Initial: Member must have a diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Must have chart note documentation of a right-heart catheterization that indicates the following hemodynamic values: mean pulmonary arterial pressure greater than 20 mmHg, pulmonary capillary wedge pressure or left atrial pressure or left ventricular end-diastolic pressure less than or equal to 15 mmHg, pulmonary vascular resistance greater than or equal to 3 wood units. Member must have WHO Functional Class II-IV symptoms. Must have a trial and failure or contraindication to sildenafil 20 mg tablets (Revatio) prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAFINLAR

Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	Members with colorectal cancer or wild-type BRAF solid tumors
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma-Initial: Approve if the member has melanoma with BRAF V600 mutations as detected by an FDA-approved test and meets either of the following (A, B, or C): A) Member has unresectable or metastatic disease with BRAF V600E mutations and medication will be used as a single agent, B) Member has unresectable or metastatic disease with BRAF V600E or V600K mutations and medication will be used in combination with trametinib (Mekinist), OR C) Member has BRAF V600E or V600K mutations with involvement of lymph node(s) following complete resection and medication will be used as adjuvant treatment in combination with trametinib (Mekinist). Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if member has NSCLC with the BRAF V600E mutation as detected by an FDA-approved test and requested medication will be used in combination with trametinib (Mekinist). Anaplastic Thyroid Cancer (ATC)-Initial: Approve if member has a diagnosis of locally advanced or metastatic ATC with BRAF V600E mutations as detected by an FDA-approved test and there are no satisfactory locoregional treatment options available for the member. Medication must be used in combination with trametinib (Mekinist). Solid Tumors-Initial: Approve if member has unresectable or metastatic solid tumors with BRAF V600E mutations as detected by an FDA-approved test. Member's disease has progressed following prior treatment and now have no satisfactory alternative

PA Criteria	Criteria Details
	treatment options. Medication must be used in combination with trametinib (Mekinist). Low-Grade Glioma (LGG)-Initial: Approve if member has LGG with BRAF V600E mutations as detected by an FDA-approved test and disease requires systemic therapy. Medication must be used in combination with trametinib (Mekinist). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAGRISSO

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has a diagnosis of NSCLC with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test that meets one of the following criteria (A, B, C, or D): A) Medication will be used as adjuvant therapy after tumor resection, B) Disease is locally advanced, unresectable (stage III) and has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy, C) Medication will be used as first-line treatment in member with metastatic disease OR D) Medication will be used in combination with pemetrexed and platinum-based chemotherapy as the first-line treatment of member with locally advanced or metastatic disease. EGFR T790M Mutations-Initial: Approve if the member has metastatic EGFR T790M mutation-positive NSCLC as detected by an FDA-approved test AND disease has progressed on or after EGFR TKI therapy. Reauthorization Criteria: Approve if the member has responded positively to therapy, without disease progression or unacceptable toxicity, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TALZENNA

Products Affected

- TALZENNA ORAL CAPSULE 0.1 MG, 0.25 MG, 0.35 MG, 0.5 MG, 0.75 MG, 1 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Initial: Approve if the member has a diagnosis of locally advanced or metastatic disease that has a deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) and is human epidermal growth factor receptor 2 (HER2) negative as determined by an FDA-approved test. Prostate Cancer-Initial: Approve if the member has metastatic castration resistant prostate cancer (mCRPC) with homologous recombination repair (HRR) gene mutations (e.g. ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C). Requested medication will be used in combination with enzalutamide (Xtandi) and a gonadotropin-releasing hormone (GnRH) analog unless the member has had a bilateral orchiectomy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

TASIGNA

Products Affected

- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Members with hypokalemia, hypomagnesemia, or long QT syndrome
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Myeloid Leukemia (CML)-Initial: Approve if the member has Philadelphia chromosome positive (Ph+) disease as detected by an FDA-approved test and meets one of the following A, B, or C: A) Member is pediatric or adult and has newly diagnosed disease in the chronic phase, B) Member is an adult who has Chronic Phase (CP) or Accelerated Phase (AP) disease resistant to or intolerant to prior therapy that included imatinib, OR C) Member is pediatric who has CP or AP disease resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TASIMELTEON

Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Non-24-Hour Sleep-Wake Disorder: 18 years and older, Smith-Magenis Syndrome (SMS): 16 years and older
Prescriber Restrictions	Prescribed by or in consultation with a physician specializing in sleep medicine
Coverage Duration	12 months
Other Criteria	Non-24-Hour Sleep-Wake Disorder (Non-24)-Initial: Approve if member is totally blind with no perception of light and has diagnosis of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Smith-Magenis Syndrome (SMS): Approve if member has a confirmed diagnosis of SMS using genetic testing (documentation required). Chart note documentation describing the sleep disturbances (e.g. early sleep onset, early awakening, etc)) and the associated symptoms (e.g. nighttime roaming, excessive daytime sleepiness, etc) must be submitted. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

TAZAROTENE

Products Affected

- *tazarotene topical cream 0.1 %*
- *tazarotene topical gel*

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic diagnoses are not covered (i.e. solar elastosis, sun damage, wrinkles, actinic damage, melasma, lentigines or freckles, hyperpigmented macules, liver spots, heliodermatosis, dermatoheliosis)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Plaque Psoriasis-Initial: Approve if the member has less than or equal to 20% of affected body surface area (BSA) and had a trial and failure or contraindication to the use of topical corticosteroids. Acne Vulgaris-Initial: Approve if the member has tried and failed A and B: A) topical antibiotic used to treat acne vulgaris (i.e. clindamycin topical, erythromycin topical) AND B) tretinoin topical. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAZVERIK

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Epitheliod Sarcoma-Initial: Approve if the member has metastatic or locally advanced disease that is not eligible for complete resection. Follicular Lymphoma-Initial: Approve if the member is an adult with relapsed or refractory disease and meets either A or B: A) According to the prescriber, there are no appropriate alternative therapies, OR B) Member's tumor is positive for an EZH2 mutation as detected by an FDA-approved test and the member has tried at least two prior systemic therapies. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TEPMETKO

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations as detected by an approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TERIFLUNOMIDE

Products Affected

- *teriflunomide*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with leflunomide (Arava) or other disease-modifying agents used for multiple sclerosis (MS), severe hepatic impairment, and pregnancy
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of relapsing multiple sclerosis (i.e. relapsing-remitting or active secondary progressive disease and clinically-isolatted syndrome). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TERIPARATIDE

Products Affected

- *teriparatide subcutaneous pen injector 20 mcg/dose (560mcg/2.24ml)*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis. Members at an increased risk for osteosarcoma (e.g. history of Paget's disease of bone, open epiphyses, bone metastaes or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton). Members with pre-existing hypercalcemia.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Postmenopausal Osteoporosis (PMO)-Initial: Approve if member is a postmenopausal woman with osteoporosis and meets either A, B, or C: A) A bone mineral density T-score of less than or equal to -2.5 at conventional skeletal sites including the total hip, femoral neck, lumbar spine (post-anterior, not lateral) or radius, B) History of fragility fracture as an adult, OR C) Bone mineral density T-score of -1.0 to -2.5 at the femoral neck or lumbar spine. Member must have a 10-year probability of either i or ii: i) a major osteeoporosis-related fracture of at least 20% based on the U.S.-adapted World Health Organization (WHO) algorithm OR ii) a hip fracture greater than or equal to 3%. For members without a history of fragility fracture or members who do not have a very high fracture risk as defined by one of the following A, B, C, or D: A) Very low T-score [less than -3.0], B) High risk for falls or history of injurious falls, C) Very high fracture probability by FRAX [e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%], OR D) Other validated fracture risk algorithm [e.g., Garvan]: Member must have a trial and failure or contraindication to one generic bisphosphonate (oral or intravenous). For

PA Criteria	Criteria Details
	primary or hypogonadal osteoporosis in men-Initial: Member has one of the following (A, B, or C): A) History of osteoporotic vertebral or hip fracture, B) Pre-treatment T-score of less than or equal to -2.5, OR C) Pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. Member must meet at least one of the following (a or b): a) Member has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR b) Member has had an oral bisphosphonate trial of at least 6 months duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. Reauthorization: If the member has taken the requested medication for two years, approve if the member is at high risk for fracture (i.e. a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density) and provider submits documentation indicating an improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TESTOSTERONE (INJECTABLE)

Products Affected

- *testosterone cypionate*
- *testosterone enanthate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Delayed puberty or induction of puberty in males-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	Delayed puberty or induction of puberty in males-6 months, All others-12 months
Other Criteria	Hypogonadism (primary or secondary) in males-Initial: Approve if the member meets all of the following criteria: 1) Member has persistent signs and symptoms of androgen deficiency prior to start of androgen therapy (i.e. depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido), 2) Member has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Delayed puberty or induction of puberty in males-Initial: Approve testosterone cypionate or enanthate. Breast cancer in females - Approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and it is deemed necessary to continue treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

TESTOSTERONE (NON-INJECTABLE)

Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)*
- *testosterone transdermal solution in metered pump w/app*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Hypogonadism (primary or secondary) in males-Initial: Approve if the member meets all of the following criteria: 1) Member has persistent signs and symptoms of androgen deficiency prior to start of androgen therapy (i.e. depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido), 2) Member has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and it is deemed necessary to continue treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

TETRABENAZINE

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Actively suicidal. Uncontrolled depression. Currently using a monoamine oxidase inhibitor or reserpine. Hepatic impairment.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Chorea associated with Huntington's Disease-Initial: Approve if member has a confirmed diagnosis of Huntington's Disease either by Huntington Disease Mutation analysis (with laboratory result indicating expanded CAG repeat of greater than or equal to 36 in the huntington gene) or a positive family history of Huntington's Disease with autosomal dominant inheritance pattern. Member must have clinical signs of Huntington's Disease to include chart documentation of a clinical work-up showing one or more of the following signs: motor (e.g. finger tapping, rigidity), oculomotor, bulbar (e.g. dysarthria, dysphagia), affective (e.g. depression), cognitive. For doses greater than 50mg/day: Member must have chart documentation of a trial of 50mg/day dose with inadequate response OR must be CYP2D6 intermediate or extensive metabolizer (as documented through CYP2D6 genotyping results), must provide documentation of slow dose titration with close monitoring of side effects. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and showing monitoring for depression and suicidal ideation. For doses greater than 50mg/day: must have chart documentation from prescriber showing inadequate efficacy of lower doses and slow titration of dose with close monitoring of side effects.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

THALOMID

Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, hematologist, dermatologist, or infectious disease specialist.
Coverage Duration	12 months
Other Criteria	Multiple Myeloma (MM)-Initial: Approve if the member has been newly diagnosed and the requested medication will used in combination with dexamethasone. Erythema Nodosum Leprosum (ENL)-Initial: Approve if the member has a diagnosis of ENL and meets either A, B, or C: A) Medication will be used as acute treatment of the cutaneous manifestations of moderate to severe disease, B) Member has moderate to severe neuritis and requested medication will not be used as monotherapy, OR C) Member will be using the requested medication as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member has a diagnosis of AML with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test and meets either of the following: A) Member will be using the medication in combination with azacitadine or as monotherapy in adults 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy, OR B) Member has relapsed or refractory disease. Myelodysplastic Syndrome (MDS)-Initial: Approve if member has diagnosis of relapsed or refractory MDS. Cholangiocarcinoma-Initial: Approve if the member has locally advanced or metastatic disease that has been previously treated. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

TOBRAMYCIN (NEBULIZATION)

Products Affected

- *tobramycin in 0.225 % nacl*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cystic fibrosis-Initial: Approve if the member has pseudomonas aeruginosa in the culture of the airway (documentation required).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOLVAPTAN

Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications containing tolvaptan, strong CYP3A inhibitors, or hypertonic saline. Members requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms. Use in members with autosomal dominant polycystic kidney disease (ADPKD) outside of FDA-approved REMS. Members who are unable to respond appropriately to thirst. Hypovolemic hyponatremia and anuria.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Approve if the member has clinically significant hypervolemic and euvolemic hyponatremia defined as serum sodium less than 125 mEq/L at baseline or less marked hyponatremia that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion) and has resisted correction with fluid restriction. Provider must have consideration of discontinuation of agents known to cause Syndrome of Inappropriate Antidiuretic Hormone (SIADH) when clinically feasible (e.g. chlorpropamide, selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, clofibrate, carbamazepine, vincristine, nicotine, narcotics, phenothiazines, butyrophenones, ifosfamide, cyclophosphamide, NSAIDs, MDMA, desmopressin, oxytocin, vasopressin, carbamazepine, oxcarbazepine). Must have CrCl greater than 10mL/min. Must be initiated and titrated in hospital setting with close serum sodium monitoring. Must be able to sense and appropriately respond to thirst. If SIADH is underlying cause of hyponatremia, the member must demonstrate all of the following: decreased plasma osmolality of less than 275 mosm/kg, increased urinary osmolality of greater than 100mosm/kg during hypotonicity, urinary

PA Criteria	Criteria Details
	sodium greater than 20mmol/L with normal dietary salt intake, clinical euvolemia, normal thyroid and adrenal function, and no recent use of diuretics within 24 hours of laboratory testing.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOLVAPTAN (JYNARQUE)

Products Affected

- *tolvaptan (polycys kidney dis) oral tablet 15 mg, 30 mg*
- *tolvaptan (polycys kidney dis) oral tablets, sequential*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A inhibitors or other V2-receptor antagonists. Members who are unable to respond appropriately to thirst. Members with uncorrected abnormal blood serum concentrations, a history of signs or symptoms of significant liver impairment or injury (Note: this does not include uncomplicated polycystic liver disease). Members with hyponatremia, uncorrected urinary outflow obstruction, and anuria.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	12 months
Other Criteria	Approve if the member has a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) confirmed via imagining or genetic testing (documentation required). Member must be at risk of rapid disease progression as indicated by either A or B (documentation required): A) Mayo Imaging Class of 1C, 1D, or 1E OR B) Historical rate of eGFR decline greater than or equal to 3 mL/min per 1.73 m2 per year. Provider attests there are no alternative explanations for loss of eGFR (e.g., vascular disease, uncontrolled hypertension, diabetic nephropathy, proteinuria at least 1 g/d) and/or acute kidney injury. If member does have alternative explanations for rapid eGFR decline, additional information (including magnetic resonance imaging or computed tomography imaging will be undertaken, if not previously performed, PROPKD score greater than 6, a family history with onset of KRT at less than 60 years of age in at least 2 first-line family members) should be acquired to ensure ADPKD as the primary reason for eGFR loss. Documentation showing the member has a current eGFR at least 25 mL/min per 1.73 m2 must be submitted. Provider attests baseline liver function tests (AST, ALT, total bilirubin) prior to

PA Criteria	Criteria Details
	initiation of therapy and will continue to monitor LFTs monthly for the first 18 months, then every 3 months thereafter. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Provider attests to continual monitoring of liver function.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- *fentanyl citrate buccal lozenge on a handle 200 mcg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRETINOIN (TOPICAL)

Products Affected

- *tretinoin topical*

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic diagnoses are not covered (i.e. solar elastosis, sun damage, wrinkles, actinic damage, melasma, lentigines or freckles, hyperpigmented macules, liver spots, heliodermatosis, dermatoheliosis)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of acne vulgaris. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRIENTINE

Products Affected

- *trientine oral capsule 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician
Coverage Duration	12 months
Other Criteria	Wilson's Disease-Initial: Approve if member has chart note documentation of how the diagnosis was confirmed including at least one of the following: A) genetic testing indicating biallelic pathogenetic mutation in ATP7B gene OR B) Two of the following clinical features (a, b, c, or d): a) liver biopsy findings consistent with Wilson's desease, b) presence of Kayser-Fleisher Ring in cornea, c) serum ceruloplasmin level less than 20 mg/dL, or 24-hour urinary excretion of copper greater than 40 micrograms (1.6 micromoles) per 24 hours. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRIKAFTA

Products Affected

- TRIKAFTA ORAL TABLETS, SEQUENTIAL

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications containing ivacaftor or severe hepatic impairment (Child-Pugh Class C)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in cystic fibrosis
Coverage Duration	12 months
Other Criteria	Initial: Member must have a diagnosis of cystic fibrosis and at least one F508del mutation in the CFTR gene. If the member's genotype is unknown, an FDA-approved cystic fibrosis mutation test must be used to confirm a mutation in the CFTR gene that is responsive to the requested medication. Provider attestation liver function tests will be assessed prior to initiation of treatement, every 3 months during the first 12 months of treatment, then at least annually thereafter. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician, absent of toxicities, and provider attestation to monitor liver function tests at least annually.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRUQAP

Products Affected

- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Approve if the member has a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has PIK2CA/AKT1/PTEN-alterations as detected by an FDA-approved test and member both A and B: A) Member has locally advanced or metastatic disease AND B) Member had progression with at least one endocrine-based regimen in the metastatic setting (i.e. anastrozole, exemestane, letrozole.) OR member had recurrence on or within 12 months of completing adjuvant endocrine therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TUKYSA

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Initial: Approve if the member has human epidermal growth factor receptor 2 (HER2)-positive disease as determined by an FDA-approved test and meets the following A, B, and C: A) Disease is advanced, unresectable or metastatic, B) Member has received one or more prior anti-HER2-based regimens in the metastatic setting, AND C) The requested medication will be used in combination with trastuzumab and capecitabine. Colorectal Cancer-Initial: Approve if the member has wild-type RAS (KRAS wild-type and NRAS wild-type) tumors as determined by an FDA-approved test and member meets the following A, B, and C: A) Member has been previously treated with a fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, B) Member has unresectable or metastatic disease, AND C) Member will be using the requested medication in combination with trastuzumab. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TURALIO

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Tenosynovial Giant Cell Tumor (TGCT)-Initial: Approve if the member has TGCT associated with severe morbidity or functional limitations. Member must be symptomatic with tumors not amenable to improvement with surgery. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TYENNE

Products Affected

- TYENNE AUTOINJECTOR
- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, targeted synthetic DMARDs, potent immunosuppressants, anti-interleukin monoclonal antibodies, or janus kinase inhibitors.
Required Medical Information	Diagnosis
Age Restrictions	RA and GCA: 18 years and older
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: RA/GCA/PJIA/SJIA: Rheumatologist.
Coverage Duration	12 months
Other Criteria	Rheumatoid Arthritis (RA)-Initial: Approve if member has diagnosis of moderately to severely active disease and member has tried and failed one of the following prior to approval: a preferred adalimumab product (Hadlima, Simlandi), a preferred ustekinumab product (Selarsdi, Yesintek), Rinvoq, Skyrizi, Otezla, or Xeljanx/XR). Polyarticular Juvenile Idiopathic Arthritis (PJIA)-Initial: Approve if member has a diagnosis of active disease and a trial and failure of one of the following prior to approval: a preferred adalimumab product (Hadlima, Simlandi), Rinvoq, or Xeljanx/XR). Systemic Juvenile Idiopathic Arthritis (SJIA)-Initial: Approve if member has a diagnosis of active disease and chart documentation of the following: history of fever for at least two weeks AND arthritis in one or more joints for at least six weeks. Member should have a history of at least one of the following: erythematous rash, generalized lymph node enlargement, hepatomegaly or splenomegaly, or pericarditis, pleuritis, or peritonitis. Giant Cell Arteritis (GCA)-Initial: Approve if documentation of temporal artery biopsy confirming diagnosis (biopsy result required) and member has received high-dose glucocorticoids (i.e. prednisone 40mg - 60mg, or maximally tolerated dose), unless member has contraindication to the use of glucocorticoids. Cytokine Release Syndrome (CRS)-Initial: Approve if the member has undergone CAR T-Cell therapy in the past two months and has severe or

PA Criteria	Criteria Details
	life-threatening CRS (e.g. hypotension, hypoxia, organ toxicity, clinical deterioration). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

UNBRANDED USTEKINUMAB SC

Products Affected

- USTEKINUMAB SUBCUTANEOUS SOLUTION
- USTEKINUMAB SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis. For all disease modifying antirheumatic drugs (DMARDs), member's previously established on biologic therapies are not required to step back and trial a conventional systemic DMARD.
Age Restrictions	N/A
Prescriber Restrictions	Plaque Psoriasis: Prescribed by or in consultation with a dermatologist. Psoriatic Arthritis: Prescribed by or in consultation with a rheumatologist or dermatologist. Crohn's Disease/Ulcerative Colitis: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	12 months
Other Criteria	All requests for Ustekinumab (Unbranded Ustekinumab) require clinical rationale why the member cannot use the preferred biosimilar formulations of Ustekinumab (Selarsdi and Yesintek) prior to approval. Plaque Psoriasis (PsO)-Initial: Approve if the member has chronic moderate to severe disease and member has tried and failed at least one systemic therapy for 3 months with inadequate results (i.e. phototherapy, methotrexate, acitretin). Crohn's Disease (CD)-Initial: Approve if the member has received a single IV loading dose within two months of initiating therapy with the requested medication and member has moderate-to-severe disease based on evidence of large or deep ulcers, strictures, or extensive areas of disease and/or evidence of stricturing, penetrating, or perianal disease on endoscopy. Ulcerative Colitis (UC)-Initial: Approve if the member has received a single IV loading dose within two months of initiating therapy with the requested medication and member has moderate-to-severe disease based on the following: A) Member presents with frequent, bloody stools that occur 6 or more times daily or frequent and heavy rectal bleeding AND B) Member has severe inflammation or ulcers as visualized on endoscopy. Psoriatic Arthritis(PsA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following

PA Criteria	Criteria Details
	(documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

UPTRAVI

Products Affected

- UPTRAVI ORAL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of pulmonary arterial hypertension (PAH) with chart notes documenting all the following are required: A) mean arterial pressure (mPAP) measured greater than or equal to 20 mmHg at rest, B) pulmonary artery wedge pressure (PAWP) measured less than or equal to 15 mmHg, AND C) pulmonary vascular resistance (PVR) greater than or equal to 2 woods units. Member must meet either A or B: A) Member has PAH WHO Group 1 confirmed by hemodynamic definitions obtained from a right heart catheterization (RHC) (documentation required) and is currently established on therapy for the diagnosis of PAH
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

USTEKINUMAB SC

Products Affected

- SELARSDI SUBCUTANEOUS SOLUTION
- SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- STELARA INTRAVENOUS
- STELARA SUBCUTANEOUS SOLUTION
- STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis. For all disease modifying antirheumatic drugs (DMARDs), member's previously established on biologic therapies are not required to step back and trial a conventional systemic DMARD.
Age Restrictions	N/A
Prescriber Restrictions	Plaque Psoriasis: Prescribed by or in consultation with a dermatologist. Psoriatic Arthritis: Prescribed by or in consultation with a rheumatologist or dermatologist. Crohn's Disease/Ulcerative Colitis: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	12 months
Other Criteria	All requests for Ustekinumab (Stelara) require clinical rationale why the member cannot use the preferred biosimilar formulations of Ustekinumab (Selarsdi and Yesintek) prior to approval. Plaque Psoriasis (PsO)-Initial: Approve if the member has chronic moderate to severe disease and member has tried and failed at least one systemic therapy for 3 months with inadequate results (i.e. phototherapy, methotrexate, acitretin). Crohn's Disease (CD)-Initial: Approve if the member has received a single IV loading dose within two months of initiating therapy with the requested medication and member has moderate-to-severe disease based on evidence of large or deep ulcers, strictures, or extensive areas of disease and/or evidence of stricturing, penetrating, or perianal disease on endoscopy. Ulcerative Colitis (UC)-Initial: Approve if the member has received a single IV loading dose within two months of initiating therapy with the requested medication and member has moderate-to-severe disease based on the following: A) Member presents with frequent, bloody stools that occur

PA Criteria	Criteria Details
	6 or more times daily or frequent and heavy rectal bleeding AND B) Member has severe inflammation or ulcers as visualized on endoscopy. Psoriatic Arthritis(PsA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following (documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VALCHLOR

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Cutaneous lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VALTOCO

Products Affected

- VALTOCO

PA Criteria	Criteria Details
Exclusion Criteria	Acute narrow-angle glaucoma
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve if the member is using the requested medication for the acute treatment of intermittent, sterotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from the member's usual seizure pattern. Member must be currently receiving maintenance antiepileptic medication(s) and will continue to receive the current maintenance therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VANFLYTA

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Members with severe hypokalemia, hypomagnesemia, long QT syndrome, or in members with a history of ventricular arrhythmias or torsades de pointes
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member has AML that is newly diagnosed and is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test. Member must be using the requested medication in combination with standard cytarabine and anthracycline induction and cytarabine consolidation or as maintenance monotherapy following consolidation chemotherapy. Provider attests member will not be using the medication as maintenance monotherapy folloowing an allogenic hematopoietic stem cell transplantation (HSCT). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VEMLIDY

Products Affected

- VEMLIDY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, transplant physician, or infectious disease physician
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has diagnosis of chronic hepatitis B confirmed by all the following A, B, and C: A) HBsAg positive or negative for at least 6 months, B) Documented evidence of active viral replication (HBeAg+ and HBV DNA greater than 100,000 copies per mL), AND C) Documented evidence of active liver disease as demonstarated by persistent elevation in serum alanine aminotransferase (ALT) greater than two times the upper limit of normal OR moderate to severe hepatitis on biopsy. Must have a trial and failure or contraindication to entecavir and tenofovir disoproxil fumarate. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VENCLEXTA

Products Affected

- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A4 inhibitors at initiation and during the ramp-up phase in members with CLL/SLL
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member has diagnosis of AML and will be using the medication in combination with azacitadine, decitabine, or low-dose cytarabine in members meeting either A or B: A) Member is newly diagnosed and 75 years or older OR B) Members who have comorbidities that preclude the use of intensive induction chemotherapy. Small Lymphocytic Lymphoma (SLL) and Chronic Lymphocytic Leukemia (CLL)-Initial: Approve if the member has a diagnosis of CLL or SLL and has tried and failed or has a contraindication to ibrutinib (Imbruvica) prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERQUVO

Products Affected

- VERQUVO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other soluble guanylate cyclase stimulators or members who are pregnant
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of heart failure with a reduced ejection fraction. Member must be symptomatic and have a left ventricular ejection fraction (LVEF) less than 45%. Must have had a recent hospitalization for heart failure (e.g., within the past 6 months) or received recent outpatient intravenous diuretics (e.g. furosemide within the past 3 months). Must have an attestation from the prescriber that the member is on at least one other drug used for chronic heart failure at maximally tolerated doses (e.g., beta-blockers, ACE inhibitors, or sacubitril/valsartan). Must have a systolic blood pressure greater than or equal to 100 mmHg. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERSACLOZ

Products Affected

- VERSACLOZ

PA Criteria	Criteria Details
Exclusion Criteria	Elderly members with dementia-related psychosis
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of treatment-resistant schizophrenia or will be used to reduce suicidal behavior in members with schizophrenia or schizoaffective disorder. Must provide clinical rationale why clozapine orally disentigrating tablet (ODT) is not expected to produce the same clinical results as would be expected with the requested medication. Member must have a trial and failure or contraindication to a generic formulary antipsychotic: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, or ziprasidone AND one of the following brand medications: Caplyta, Rexulti, Secuado, or Vraylar. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative as detected by an FDA-approved test and meets either A, B, C, or D: A) Member has early breast cancer that is node-positive at high risk of recurrence (e.g. members with greater than or equal to 4 positive lymph nodes or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease or tumor size greater than or equal to 5 cm) and will be using the requested medication in combination with endocrine therapy (i.e. anastrozole, exemestane), B) Member has advanced or metastatic disease and will be using the requested medication in combination with an aromatase inhibitor (i.e. letrozole, anastrozole) as initial endocrine therapy, C) Member has advanced or metastatic disease progression following endocrine therapy and will be using the requested medication in combination with fulvestrant, OR D) Member has advanced or metastatic disease progression following endocrine therapy and prior chemotherapy in the metastatic setting. Requested medication will be used as monotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIGABATRIN

Products Affected

- *vigabatrin*
- *vigadrone*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Complex Partial Seizures-Initial: Approve if the member as a diagnosis of refractory complex partial seizures (i.e. focal impaired awareness seizures) and meets the following (A, B, and C): A) Member has a trial and failure to two combination anticonvulsant regimens where at least one of the medications contains phenytoin or carbamazepine, B) Member will be using the requested medication in combination with at least one other anticonvulsant (i.e. lamotrigine, topiramate), AND C) Member will undergo vision testing prior to beginning treatment. Infantile Spasms: Initial: Approve if the member has diagnosis of infantile spasms and medication will be used as monotherapy for members aged 1 month to 2 years of age for whom the potential benefit outweighs the potential risk of vision loss. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician and memberwill continue to undergo vision testing at least every 3 months during treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

VITRAKVI

Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of solid tumors that meets all the following A, B, and C: A) Member has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation as determined by an FDA-approved test, B) tumors are metastatic or surgical resection is likely to result in severe morbidity, AND C) there are no satisfactory alternative treatments or the patient has disease progression following treatment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an approved test and member will be using the requested medication as first-line treatment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VONJO

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A4 inhibitors or inducers
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-Initial: Approve if the member has a platelet count of less than 50 X 10 9/L (less than 50,000 cells/mcL) and a diagnosis of intermediate-2 or high-risk disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VORANIGO

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation as detected by an approved test. Member will be using the requested medication as monotherapy following surgery including biopsy, sub-total resection, or gross total resection. Provider attests liver laboratory tests (AST, ALT, GGT, total bilirubin and ALP) have been monitored prior to the start of the requested medication and monitoring will continue every 2 weeks during the first two months of treatment, then monthly for the first 2 years of treatment. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

VORICONAZOLE (ORAL)

Products Affected

- *voriconazole oral suspension for reconstitution*
- *voriconazole oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with rifampin, carbamazepine, long-acting barbiturates, efavirenz, ritonavir, rifabutin, ergot alkaloids, and St. Johns Wort due to risk of loss of efficacy. Coadministration with naloxegol, tolvaptan, finerenone and lurasidone due to risk of adverse reactions. Coadministration with venetoclax at initiation and during the ramp-up phase in patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) due to increased risk of adverse reactions. Coadministration with pimozide, quinidine, sirolimus or ivabradine due to risk of serious adverse reactions.
Required Medical Information	Diagnosis, For suspension: must have chart note documentation of the clinical rationale for why tablets cannot be used.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	Approve if the member has a diagnosis of either A, B, C, or D (Lab results and documentation required): A) invasive aspergillosis, B) candidemia in non-neutropenics and other deep tissue Candida infections, C) esophageal candidiasis, OR D) serious fungal infections caused by Scedosporium apiospermum and Fusarium species including Fusarium solani, in members intolerant of, or refractory to, other therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

VOWST

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or infectious disease specialist
Coverage Duration	30 days
Other Criteria	Initial: Approve if the member has a diagnosis of recurrent Clostridioides difficile infection (CDI). Provider must submit documentation of a stool test positive for toxigenic Clostridioides difficile. Must have a trial and failure or contraindication to fecal microbiota, live-jslm and standard of care treatment (defined as 10-21 days of treatment with vancomycin 125mg orally four times daily or fidaxomycin (Dificid) 200mg orally twice daily) within 2-4 days before initiating requested medication. Member must drink 296 mL of magnesium citrate on the day before and at least 8 hours prior to taking the first dose of medication. Members unable to take magnesium citrate due to impaired kidney function should receive polyethylene glycol electrolyte solution instead. Reauthorization: Additional authorizations for treatment are made on a case-by-case basis, are subject to the above criteria, and require chart documentation describing the previous response and clinical rationale for re-treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	Yes

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

VUMERITY

Products Affected

- VUMERITY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of relapsing forms of multiple sclerosis (RRMS). Member must have tried and failed one generic MS disease modifying agent prior to approval. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

WELIREG

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Renal Cell Carcinoma (RCC)-Initial: Approve if the member has advanced disease following treatment with both A and B: A) One programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND B) One vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). von Hippel-Lindau Disease (VHL)-Initial: Approve if the member has a VHL germline alteration as detected by genetic testing and meets both A and B): A) Member does not require immediate surgery AND C) Member requires therapy for one of the following conditions (i, ii, iii, or iv): i) Central nervous system hemangioblastomas, ii) Pancreatic neuroendocrine tumors, iii) Renal cell carcinoma, OR iv) Retinal hemangioblastoma. Pheochromocytoma or Paragaglioma (PPGL)-Initial: Approve if the member has documented histopathological diagnosis of pheochromocytoma or PPGL. Member must have locally advanced, unresectable, or metastatic disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

WINREVAIR

Products Affected

- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a clinician with expertise in treating patients with Pulmonary Arterial Hypertension
Coverage Duration	12 months
Other Criteria	Approve if the member has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1. Diagnosis must been confirmed with hemodynamic definitions obtained from a right heart catheterization (RHC) and chart notes documenting all the following are required: A) mean arterial pressure (mPAP) measured greater than or equal to 20 mmHg at rest, B) pulmonary artery wedge pressure (PAWP) measured less than or equal to 15 mmHg, AND C) pulmonary vascular resistance (PVR) greater than or equal to 2 woods units. Member must be established, intolerant, or have a contraindication to an endothelin receptor antagonist and a PDE-5 inhibitor. Reauthorization: Approve if the patient has responded to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XALKORI

Products Affected

- XALKORI ORAL CAPSULE
- XALKORI ORAL PELLET 150 MG, 20 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Dignosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease that meets either A or B: A) Disease is anaplastic lymphona kinase (ALK) positive as detected by an FDA approved test. Member must have a trial and failure of alectinib (Alecensa) prior to approval or a medical reason as to why it cannot be started or continued OR B) Disease is ROS1-positive as detected by an FDA approved test. Anaplastic Large Cell Lymphoma (ALCL)-Initial: Approve if the member has systemic disease that is ALK-positive as detected by an FDA-approved test that is relapsed or refractory. Inflammatory Myofibroblastic Tumor (IMT)-Initial: Approve if member has unresectable, recurrent, or refractory disease that is ALK-positive as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

XDEMVY

Products Affected

- XDEMVY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	6 weeks
Other Criteria	Initial: Approve if the member has a diagnosis of blepharitis due to Demodex infestation confirmed by the presence of collarettes on the lashes. Reauthorization: Treament beyond 6 weeks (42 days) has not been FDA approved. Additional authorizations for treatment are made on a case-by-case basis, are subject to the above criteria, and require chart documentation describing the previous response and clinical rationale for re-treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

XELJANZ

Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics, targeted synthetic DMARDs, potent immunosuppressants, anti-interleukin monoclonal antibodies, or janus kinase inhibitors.
Required Medical Information	Diagnosis, For all pre-requisite drug trials, members who have already been on biologic therpies not required to step back and try a traditional systemic agent.
Age Restrictions	AS/RA/UC: 18 years and older
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: RA/AS/JRA/JIA-Rheumatologist. PsA-Rheumatologist or dermatologist. UC-Gastroenterologist
Coverage Duration	12 months
Other Criteria	Psoriatic Arthritis(PsA)-Initial: Approve if the member has active disease as determined by the presence of at least one of the following (documentation required): actively inflamed joints, dactylitis, enthesitis, axial disease, active skin or nail involvement, or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Member must have a trial and failure or contraindication to a tumor necrosis factor inhibitor (TNFi). Ulcerative Colitis (UC)/Rheumatoid Arthritis (RA)-Initial: Approve if the member has moderately to severely active disease and has had a trial and failure or contraindication to a TNFi. Ankylosing Spondylitis (AS)-Initial: Approve if the member has active disease and has had a trial and failure or contraindication to a TNFi. Polyarticular Juvenile Idiopathic Arthritis (PJIA)-Approve if member has had a trial and failure or a contraindication to a tumor necrosis factor inhibitor (TNFi). Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XERMELO

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Initial: Approve if the member has carcinoid syndrome diarrhea and meets all the following (A, B, and C): A) Member has been on somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]), B) the member continues to have at least four bowel movements per day despite treatment with SSA therapy, AND C) Requested medication will be used concomitantly with a SSA therapy. Reauthorization: Approve if the member is continuing to take the requested medication with a SSA therapy for carcinoid syndrome diarrhea and has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XGEVA

Products Affected

- OSENVELT
- WYOST

PA Criteria	Criteria Details
Exclusion Criteria	Members with hypocalcemia. Concomitant use with other bisphosphonate therapies
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	Yes
Prerequisite Therapy Required	Yes

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	Travelers Diarrhea complicated by fever or blood in stool or diarrhea due to pathogens other than Escherichia coli
Required Medical Information	Diagnosis
Age Restrictions	Travelers Diarrhea: 12 years or older, HE and IBS-D: 18 years or older
Prescriber Restrictions	For hepatic encephalopathy: No prescriber restriction. For IBS-D: Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician.
Coverage Duration	Traveler's Diarrhea and IBS-D: 14 days. Hepatic Encephalopathy: 12 months
Other Criteria	Travelers Diarrhea (TD): Approve if provider attest member's diagnosis has not been complicated by fever nor bloody stools AND TD is caused by non-invasive strains of E. coli. Member must have previous treatment, intolerance or contraindication to ciprofloxacin, levofloxacin, or azithromycin. Irritable bowel syndrome with Diarrhea (IBS-D)-Approve if member has diagnosis of diarrhea-predominant irritable bowel syndrome (IBS-D). Must have previous treatment, intolerance or contraindication of loperamide AND antispasmodic (e.g. dicyclomine) with inadequate response to these therapies. Must have chart note documentation on how the diagnosis was confirmed. Reauthorization-IBS-D: Must have chart note documentation indicating recurrence. Recurrence must not have been treated more than twice with the the same regimen. Hepatic Encephalopathy (HE)-Initial: Approve if member has diagnosis of HE. Must have previous treatment, intolerance or contraindication of lactulose. Reauthorization-HE: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOLAIR

Products Affected

- XOLAIR SUBCUTANEOUS AUTO-INJECTOR 150 MG/ML, 300 MG/2 ML, 75 MG/0.5 ML
- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 300 MG/2 ML, 75 MG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with any other biologics for same indication(s) or Palforzia (peanut allergen powder)
Required Medical Information	Diagnosis and Member's weight. Moderate to severe persistent asthma-Initial: Approve if member has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, AND member's asthma is still uncontrolled as defined by one of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, c) Member has a FEV1 less than 80 percent predicted (90 percent for 6-18 years), D) Member has an FEV1/FVC less than 0.80 (0.90 for 6-18 years) OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy. Member must have a baseline IgE level of at least 30 IU/mL. Member must have a either A) positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or B) RAST for one or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores). Member must use medication in combination with an inhaled corticosteroid (ICS) AND one additional asthma controller (e.g. LAMA, LABA) or have a contraindication to therapies. Reauthorization: Approve if member continues to be on combination therapy with an inhaled corticosteroid and has responded positively to therapy as determined by the prescribing physician.
Age Restrictions	12 months
Prescriber Restrictions	All indications must be prescribed by or in consultation with the following: Moderate to severe persistent asthma: An allergist, immunologist, or pulmonologist. CIU: An allergist, immunologist, or dermatologist.

PA Criteria	Criteria Details
	CRSwNP: An allergist, immunologist, or otolaryngologist. Food Allergies: An allergist or immunologist.
Coverage Duration	12 months
Other Criteria	Chronic Spontaneous Urticaria (CSU)-Initial: Approve if member has a diagnosis of CSU with chart note documentation of all the following (A, B, and C): A) Urticaria has been present for no less than 6 weeks, B) Member experiences spontaneous occurence of wheals or hives that are pruritic in nature, not painful, more than 3 days per week, AND C) Symptoms persist despite taking doses of second generation H1-antihistamines (e.g. cetirizine, fexofenadine) for at least two weeks. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Nasal Polyps (CRSwNP)-Initial: Approve if the member has chart note documentation confirming diagnosis including presence of nasal polyps evidenced by nasal endoscopy or sinus computed tomography (CT) scan and has two ore more symptoms for at least three months: nasal obstruction, rhinorrhea, or reduction/loss of smell. Member has a baseline IgE level at least 30 IU/ml AND is currently receiving therapy with an intranasal corticosteroid. Reauthorization: Approve if the member continues to receive therapy with an intranasal corticosteroid and has responded to therapy. IgE-Mediated Food Allergy-Initial: Approve if member meets all A, B, C and D: A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test to one or more foods and positive in vitro test for IgE to one or more foods, C) history of allergic reaction that meets all of the following: i) member demonstrated signs and symptoms of a significant systemic allergic reaction, ii) reaction occurred within a short period of time following a known ingestion of the food, and iii) prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, AND D) member has been prescribed an epinephrine auto-injector. Reauthorization: Approve if the member has responded to therapy and additonally for CRSwNP only, member continues to receive therapy with an intranasal corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Acute Myeloid Leukemia (AML)-Initial: Approve if the member has a diagnosis of relapsed or refractory AML with an FLT3 mutation as detected by an FDA-approved test. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

XPOVIO

Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (10 MG X 4), 40 MG/WEEK (40 MG X 1), 40MG TWICE WEEK (40 MG X 2), 60 MG/WEEK (60 MG X 1), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (40 MG X 2), 80 MG/WEEK (80 MG X 1), 80MG TWICE WEEK (160 MG/WEEK)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Multiple Myeloma (MM)-Initial: Approve if the member has a diagnosis of multiple myeloma and meets either of the following (A or B): A) Member has received at least one prior therapy for MM and the requested medication will be taken in combination with dexamethasone OR B) Member has received at least four prior regimens for MM and disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. Member must take the requested medication in combination with dexamethasone. Diffuse Large B-cell Lymphoma (DLBCL)-Initial: Approve if the member has a diagnosis of relapsed or refractory disease, not otherwise specified, including DLBCL arising from follicular lymphoma, after at least two prior lines of systemic therapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XTANDI

Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a diagnosis of prostate cancer and meets either: A) Disease is castration-resistant and the member will be using the medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the member has had a bilateral orchiectomy, B) Disease is non-metastatic, castration-sensitive with biochemical recurrence at high risk for metastasis (i.e. prostate-specific antigen (PSA) doubling time less than or equal to 9 months), C) Disease is metastatic, castration-sensitive and the member will be using the medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the member has had a bilateral orchiectomy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

ZARXIO

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN - hematologist.
Coverage Duration	chemo/SCN/AML-6mo.MDS-3mo.PBPC,BMT- 3mo. Other-12mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZEJULA

Products Affected

- ZEJULA ORAL TABLET 100 MG, 200 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-Initial: Approve if the member will be using the requested medication for maintenance therapy and member meets either A or B: A) Disease is positive for a deleterious or suspected deleterious germline BRCA mutation as detected by an FDA-approved test and member had a complete or partial response to platinum-based chemotherapy OR B) Member has advanced disease and a complete or partial response to first-line platinum-based chemotherapy. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	Members with wild-type BRAF melanoma
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Initial: Approve if the member has a BRAF V600 mutation as detected by an FDA-approved test and meets either A or B: A) Member has unresectable or metastatic melanoma with a BRAF V600E mutation OR B) Member has Erdheim-Chester disease. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZEPOSIA

Products Affected

- ZEPOSIA
- ZEPOSIA STARTER KIT (28-DAY)
- ZEPOSIA STARTER PACK (7-DAY)

PA Criteria	Criteria Details
Exclusion Criteria	MS-Concurrent use with other disease-modifying agents used for multiple sclerosis.UC- Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis
Required Medical Information	Diagnosis
Age Restrictions	UC-18 years and older
Prescriber Restrictions	MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist
Coverage Duration	12 months
Other Criteria	Multiple Sclerosis (MS)-Initial: Approve if the member has tried generic dimethyl fumarate. Note: Prior use of brand Tecfidera, Bafiertam or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. Ulcerative Colitis (UC)-Initial: Approve if the member has tried a preferred ustekinumab product (Selarsdi, Yesintek) (a trial of Simponi SC or infliximab would also count). Reauthorization: Approve if the member has been established on Zeposia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Cutaneous T-Cell Lymphoma (CTCL)-Initial: Approve if the member has a diagnosis of CTCL that is progressive, persistent, or recurrent following two prior systemic therapies. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZONISADE

Products Affected

- ZONISADE

PA Criteria	Criteria Details
Exclusion Criteria	Members with a hypersensitivity to sulfonamides.
Required Medical Information	Diagnosis and must have documentation showing that administration via nasogastric tube is required OR documentation of inability to swallow an intact tablet.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Initial: Approve if member has a diagnosis of partial-onset seizures (i.e. focal seizures). Member must have tried and failed or have a contraindication to two or more generic formulary antiepileptic medications used to treat the same indication: levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin, or topiramate. Member must be using the medication as adjunctive treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Initial: 6 months, Reauthorization: 12 months
Other Criteria	Initial: Approve if the member has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) and meets both A and B: A) Diagnosis of CDD was confirmed by genetic testing (test results required) AND member will be monitored for the emergence or worsening of depression, suicidal thoughts/behavior, unusual changes in mood or behavior. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZURZUVAE

Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	Previous treatment with the requested medication during the current episode of postpartum depression
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist
Coverage Duration	14 days
Other Criteria	Approve if the member has a diagnosis of postpartum depression based on the following: A) Member has five or more of the following symptoms that have been present during the same two-week period and represent a change from previous functioning (Note: one of the symptoms is either depressed mood or loss of interest or pleasure): 1) depressed mood most of the day, nearly every day, 2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day, 3) significant weight loss when not dieting or weight gain (e.g. a change of more than 5% in a month), or change in appetite nearly every day, 4) insomnia or hypersomnia nearly every day, 5) psychomotor agitation or retardation nearly every day that are observable by others, 6) fatigue or loss of energy nearly every day, 7) feelings of worthlessness or excessive or inappropriate guilt, 8) diminished ability to think or concentrate, or indecisiveness, nearly every day, 9) recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attemmpt or a specific plan for committing suicide, B) The episode is not attributable to the psysiologoical effects of a substance or to another medical condition (i.e. serious medical illness or disability, financial hardships), AND C) The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic

PA Criteria	Criteria Details
	disorders. Member had symptom onset beginning during the third trimester of pregnancy or up to 4 weeks post-delivery and member is less than or equal to 12 months postpartum. Member must not currently pregnant. Reauthorization is not permitted.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Chronic Lymphocytic leukemia (CLL)-Initial: Member must have a confirmed diagnosis of CLL. Member must have tried and failed ibrutinib (Imbruvica) prior to approval. Requested medication must be for relapsed disease and used in combination with rituximab, in members for whom rituximab alone would be considered appropriate therapy due to other co-mobidities.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYKADIA

Products Affected

- ZYKADIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Initial: Approve if the member has metastatic disease that is anaplastic lymphona kinase (ALK) positive as detected by an FDA approved test. Member must have a trial and failure of alectinib (Alecensa) prior to approval or a medical reason as to why it cannot be started or continued. Reauthorization: Approve if the member has responded positively to therapy as determined by the prescribing physician. Documentation required that disease progression has not occurred.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PART B VERSUS PART D

Products Affected

- *acetylcysteine solution 100 mg/ml (10 %), 200 mg/ml (20 %)*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 2.5 mg/0.5 ml, 5 mg/ml*
- *amphotericin b injection recon soln 50 mg*
- *amphotericin b liposome intravenous suspension for reconstitution 50 mg*
- *aprepitant oral capsule 125 mg, 40 mg, 80 mg*
- *aprepitant oral capsule,dose pack 125 mg (1)- 80 mg (2)*
- *arformoterol inhalation solution for nebulization 15 mcg/2 ml*
- *azathioprine oral tablet 50 mg*
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- CLINIMIX 5%/D15W SULFITE FREE INTRAVENOUS PARENTERAL SOLUTION 5 %
- CLINIMIX 4.25%/D10W SULF FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX 4.25%/D5W SULFIT FREE INTRAVENOUS PARENTERAL SOLUTION 4.25 %
- CLINIMIX 5%-D20W(SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 5 %
- *cromolyn inhalation solution for nebulization 20 mg/2 ml*
- *cyclophosphamide oral capsule 25 mg, 50 mg*
- CYCLOPHOSPHAMIDE ORAL TABLET 25 MG, 50 MG
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- *dronabinol oral capsule 10 mg, 2.5 mg, 5 mg*
- ENGERIX-B (PF) INTRAMUSCULAR SUSPENSION 20 MCG/ML
- ENGERIX-B (PF) INTRAMUSCULAR SYRINGE 20 MCG/ML
- ENGERIX-B PEDIATRIC (PF) INTRAMUSCULAR SYRINGE 10 MCG/0.5 ML
- *everolimus (immunosuppressive) oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- FIRMAGON KIT W DILUENT SYRINGE SUBCUTANEOUS RECON SOLN 120 MG, 80 MG
- *formoterol fumarate inhalation solution for nebulization 20 mcg/2 ml*
- *gengraf oral capsule 100 mg, 25 mg*
- *granisetron hcl oral tablet 1 mg*
- HEPLISAV-B (PF) INTRAMUSCULAR SYRINGE 20 MCG/0.5 ML
- IMOVAX RABIES VACCINE (PF) INTRAMUSCULAR RECON SOLN 2.5 UNIT
- *intralipid intravenous emulsion 20 %*
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution for nebulization 0.5 mg-3 mg(2.5 mg base)/3 ml*
- JYLAMVO ORAL SOLUTION 2 MG/ML
- JYNNEOS (PF) SUBCUTANEOUS SUSPENSION 0.5X TO 3.95X 10EXP8 UNIT/0.5
- *levalbuterol hcl inhalation solution for nebulization 0.31 mg/3 ml, 0.63 mg/3 ml, 1.25 mg/0.5 ml, 1.25 mg/3 ml*
- *methotrexate sodium (pf) injection solution 25 mg/ml*
- *methotrexate sodium injection solution 25 mg/ml*
- *methotrexate sodium oral tablet 2.5 mg*

- *methylprednisolone oral tablet 16 mg, 32 mg, 4 mg, 8 mg*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension for reconstitution 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet,delayed release (dr/ec) 180 mg, 360 mg*
- *ondansetron hcl oral solution 4 mg/5 ml*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet,disintegrating 4 mg, 8 mg*
- *pentamidine inhalation recon soln 300 mg*
- PLENAMINE INTRAVENOUS PARENTERAL SOLUTION 15 %
- *premasol 10 % intravenous parenteral solution 10 %*
- PROGRAF ORAL GRANULES IN PACKET 0.2 MG, 1 MG
- RABAVERT (PF) INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION 2.5 UNIT
- RECOMBIVAX HB (PF) INTRAMUSCULAR SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5 ML
- RECOMBIVAX HB (PF) INTRAMUSCULAR SYRINGE 10 MCG/ML, 5 MCG/0.5 ML
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- *travasol 10 % intravenous parenteral solution 10 %*
- TROPHAMINE 10 % INTRAVENOUS PARENTERAL SOLUTION 10 %
- XATMEP ORAL SOLUTION 2.5 MG/ML
- YUPELRI INHALATION SOLUTION FOR NEBULIZATION 175 MCG/3 ML

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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