ACTEMRA

Products Affected

- ACTEMRA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried
Age Restrictions	N/A
Prescriber Restrictions	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with the following drugs will be counted towards meeting the try TWO requirement: Cimzia, Kevzara, infliximab, golimumab SC/IV, or a non-preferred adalimumab product will also count.). OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Rinvoq, Xeljanz or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with the drug Kevzara, infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement.), OR B) patient has heart failure or a previously treated lymphoproliferative disorder.Systemic-onset JIA, approve for patients who have tried one other systemic agent for SJIA (eg, a corticosteroid [oral, IV], a conventional synthetic DMARD [eg, MTX, leflunomide, sulfasalazine], Kineret (anakinra), or Ilaris (canakinumab for SC injection), or a 1-month trial of a nonsteroidal anti-inflammatory drug [NSAID]). Giant cell arteritis, initial-approve if the patient has tried one

PA Criteria	Criteria Details
	systemic corticosteroid. Cont tx, RA/PJIA/SJIA/GCA - approve if the pt had a response as determined by the prescriber. Cytokine release syndrome associated with chimeric antigen receptor (CAR) T-Cell therapy-approve. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Yuflyma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ACTEMRA SQ

Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	Interstitial lung disease-18 years and older (initial and continuation)
Prescriber Restrictions	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
Coverage Duration	12 months
Other Criteria	RA initial - approve if the patient meets one of the following (A or B): patient has tried TWO of the following drugs in the past: an adalimumab product, Enbrel, Orencia, Rinvoq or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with the following drugs will be counted towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA initial, approve if the patient meets one of the following (A or B): patient has tried TWO of the following: Enbrel, Orencia, Rinvoq, Xeljanz, or an adalimumab product (Note: if the patient does not meet this requirement, previous trial with the drug infliximab will be counted towards meeting the try TWO requirement), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt had a response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis initial-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Interstitial lung disease assoc with systemic sclerosis, Cont tx-approve if the patient had adequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

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)-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)-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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADALIMUMAB OTHER

Products Affected

- CYLTEZO(CF) PEN
- CYLTEZO(CF) PEN CROHN'S-UC-HS
- CYLTEZO(CF) PEN PSORIASIS-UV
- CYLTEZO(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.4 ML, 40 MG/0.8 ML
- YUFLYMA(CF) AI CROHN'S-UC-HS
- YUFLYMA(CF) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- YUFLYMA(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	CD, 6 or older (initial). UC, 5 or older (initial). PP-18 years and older (initial)
Prescriber Restrictions	Init tx only-RA/JIA/JRA/Ankylosing spondylitis, prescr/consult w/rheum. PsA, prescr/consult w/rheum or derm. PP, prescr/consult w/derm. UC/ CD, prescr/consult w/gastro. HS, presc/consult w/derm. UV, prescr/consult w/ophthalmologist.
Coverage Duration	1 year
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. Plaque psoriasis (PP) initial. approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for

PA Criteria	Criteria Details
	psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). cont tx - must respond to tx as determined by prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADBRY

Products Affected

- ADBRY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody (i.e Dupixent, Cinqair, Fasenra, Nucala, Tezspire, or Xolair)
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Dermatologist, allergist, or immunologist
Coverage Duration	Init-4mo, Cont-1 yr
Other Criteria	Initial-Approve if members meets both A and B criteria: A-member has used at least 1 med, med-high, high, and/or super-high-potency prescription topical corticosteroid OR atopic dermatitis is affecting ONLY face, eyes/lids, skin folds, and/or genitalia AND member tried tacrolimus ointment B-member had inadequate response with previous treatments.Cont-pt responded to Adbry.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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), prescriber specialty, other medications tried or used in combination with requested medication
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

AG HARVONI

Products Affected

- LEDIPASVIR-SOFOSBUVIR

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	N/A
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

AIMOVIG

Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Ajovy, Vyepti or Emgality
Required Medical Information	Diagnosis, number of migraine headaches per month, prior therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic pharmacologic therapy(e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AKEEGA

Products Affected

- AKEEGA

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	Prostate cancer- Approve if the patient meets the following (A, B, C, and D): A) Patient has metastatic castration-resistant prostate cancer, AND B) Patient has a BReast CAncer (BRCA) mutation, 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. Patient has had a bilateral orchiectomy
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALDURAZYME

Products Affected

- ALDURAZYME

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
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 lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient alpha-L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR has a molecular genetic test demonstrating alpha-L-iduronidase gene mutation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALECENSA

Products Affected

- ALECENSA

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	NSCLC-Approve if the member meets the following A or B: A) Member must have ALK-positive metastatic NSCLC as detected by an FDA approved test OR B) Member will be using medication as adjuvant treatment following tumor resection of ALK-positive NSCLC (tumors greater than or equal to 4 cm or node positive) as detected by an FDA approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	ALK status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Metastatic NSCLC, must be ALK-positive, as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ALVAIZ

Products Affected

- ALVAIZ ORAL TABLET 18 MG, 36 MG, 54 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	Myelodysplastic Syndrome (MDS)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	ITP, Aplastic Anemia-Hematologist or oncologist. Hepatitis C-Gastroenterologist, hematologist, hepatologist, or infectious disease specialist.
Coverage Duration	All indications-Initial-6 months Continuation-12 months
Other Criteria	Initial-Refractory Severe Aplastic Anemia (SAA)-Approve if member has diagnosis of SAA as evidenced by TWO of the following: Absolute neutrophil count (ANC) less than 0.5 x 109/L, Platelet count is less than 20 x 109/L, Reticulocyte count less than 1% corrected or less than 60,000/microL. Must have documentation confirming platelet levels are less than 50 x 109/L. 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-Approve if member has diagnosis. Must have documentation confirming platelet levels are less than 75 x 109/L. Provider attests requested medication will be used to achieve the target platelet count necessary to initiate antiviral therapy and to avoid reductions in concomitant interferon-based therapy. Chronic Immune Thrombocytopenia (ITP)-Approve if member has diagnosis of ITP. Must have 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-Chronic Hepatitis C Infection-Associated Thrombocytopenia-Approve if member continues to receive interferon-based therapy. All Other Indications (including Chronic

PA Criteria	Criteria Details
	Hepatitis C Infection-Associated Thrombocytopenia)-Approve if platelet count meets one of the following: less than 50 x 109/L, greater than or equal to 50 x 109/L to 200 x 109/L, 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. Provider must attest to regularly monitoring liver function and hematology laboratory tests. Provider attests member is not experiencing any signs or symptoms of hepatic injury or thromboembolism. Provider attests requested medication will not be used in combination with another thrombopoietin receptor agonist or with Tavalisse (fostamatinib).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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
- *fluvoxamine oral capsule,extended release 24hr*
- 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 approval - Approve if member has had a trial and failure with either two preferred SSRIs or one preferred SSRI AND venlafaxine ER Continuation of therapy - Approve if member has positive response to therapy
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ANTIFUNGALS (IV)

Products Affected

- *fluconazole in nacl (iso-osm)*
- *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

ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent biologic therapy
Required Medical Information	N/A
Age Restrictions	Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.
Prescriber Restrictions	Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, derm, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum
Coverage Duration	CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont
Other Criteria	CAPS renewal - approve if the patient has had a response as determined by the prescriber. DIRA initial-approve if the patient weighs at least 10 kg, genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. DIRA cont-approve if the patient has responded to therapy. Pericarditis initial-approve if the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Continuation-approve if the patient has had a clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication history of a multidrug regimen which includes a macrolide antibiotic (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin)
Age Restrictions	MAC-18 years and older (initial therapy)
Prescriber Restrictions	MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis
Coverage Duration	1 year
Other Criteria	MAC Lung disease, initial-approve if the patient has a positive sputum culture for mycobacterium avium complex and the culture was collected within the past 3 months and was collected after the patient has completed a background multidrug regimen, the Mycobacterium avium complex isolate is susceptible to amikacin with a minimum inhibitor concentration (MIC) of less than or equal to 64 microgram/mL AND Arikayce 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). MAC Lung Disease, continuation-approve if Arikayce will be used in conjunction with a background multidrug regimen AND i. Patient meets ONE of the following criteria (a or b):a)patient has not achieved negative sputum cultures for Mycobacterium avium complex OR b) patient has achieved negative sputum cultures for Mycobacterium avium complex for less than 12 months.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

ATYPICAL ANTIPSYCHOTICS

Products Affected

- CAPLYTA
- FANAPT ORAL TABLET
- FANAPT ORAL TABLETS,DOSE PACK
- LYBALVI
- REXULTI ORAL TABLET
- VRAYLAR 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	Trial and failure, contraindication, or intolerance to TWO of the following generic formulary atypical antipsychotic agents: aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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-approve if the patient has locally advanced or metastatic disease, patient has ROS1-positive non-small cell lung cancer and the mutation was detected by an approved test. Solid Tumors-approve if the member has solid tumors meeting all the following a, b, and c: a) has a neurotropic tyrosine receptor kinase (NTRK) gene fusion, b) are locally advanced or metastatic or where surical resection is likely to result in severe morbidity, and c) have progressed following treatment or have no satisfactory alternative therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

AUSTEDO

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR TITRATION KT(WK1-4) ORAL TABLET, EXT REL 24HR DOSE PACK 12-18-24-30 MG, 6 MG (14)-12 MG (14)-24 MG (14)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
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	TD: Initial - 3 months. Reauth - 12 months. Chorea associated with Huntington's disease: 1 year.
Other Criteria	Tardive Dyskinesia (TD) (initial): Member must have diagnosis of TD with 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 (reauth): Documentation of positive clinical response to therapy. Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	Relapsing forms of multiple scleroisis (MS)-Approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BALVERSA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Urothelial Carcinoma - Approve is the member meets A, B, and C: A) Member must have locally advanced or metastatic disease AND B) Member has susceptible fibroblast growth factor receptor 3 (FGFR3) genetic alterations AND C) Member disease has progressed on or after at least one line of prior systemic therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BENLYSTA

Products Affected

- BENLYSTA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or Lupkynis
Required Medical Information	Diagnosis, medications that will be used in combination, autoantibody status
Age Restrictions	N/A
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont
Other Criteria	Lupus Nephritis Initial-approve if the patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]. Cont-approve if the patient has responded to the requested medication. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA] AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

BESREMI

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other interferon products
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BETASERON/EXTAVIA

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	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	Relapsing forms of multiple scleroisis (MS)-Approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BOSENTAN/AMBRISENTAN

Products Affected

- *ambrisentan*
- *bosentan*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath
Age Restrictions	N/A
Prescriber Restrictions	For treatment of pulmonary arterial hypertension, ambrisentan or bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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. For CML, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, patient must have Ph-positive CML
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

BRAFTOVI

Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer- approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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 AND an inadequate response or intolerance to two generic antiepileptic drugs (i.e. levetiracetam, topiramate, lamotrigine) Reauth-Approve if member has been established on medication
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BRUKINSA

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Mantle Cell Lymphoma-Approve if the patient has tried at least one prior therapy. Marginal zone lymphoma-Approve if the patient has tried at least one anti-CD20 based regimen. Waldenstrom macroglobulinemia-Approve. Chronic Lymphocytic Leukemia (CLL)/Small lymphocyctic lymphoma (SLL)-Approve. Relapsed or Refractory Follicular Lymphoma (FL)-Approve if patient has tried at least two or more systemic regimens AND pt will be using in combination with obinutuzumab.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

BYLVAY

Products Affected

- BYLVAY ORAL CAPSULE 1,200 MCG, 400 MCG
- BYLVAY ORAL PELLET 200 MCG, 600 MCG

PA Criteria	Criteria Details
Exclusion Criteria	PFIC Type 2 with specific ABCB11 variant resulting in non-functional or complete absence of bile salt export pump (BSEP) protein OR patients with prior or active hepatic decompensation events (e.g. variceal hemorrhage, ascites, hepatic encephalopathy)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Hepatologist or gastroenterologist
Coverage Duration	Initial-6 months Reauth-12 months
Other Criteria	Initial-Alagille Syndrome-Approve if member has a confirmed diagnosis of cholestatic pruritis associated with Alagille Syndrome. Must provide lab results of genetic testing confirming a JAG1 or NOTCH2 deletion or mutation and serum bile acid concentration above the upper limit of normal. Must have trial with an inadequate response or significant side effect or contraindication to at least ONE medications for ALGS-associated pruritis (e.g. ursodeoxycholic acid (Ursodiol), rifampin) AND maralixibat (Livmarli). Must provide baseline Itch Reported Outcome (ItchRO) score and chart documentation describing the pruritis with the associated symptoms (i.e. sleep disturbances, difficulty concentrating during the day). Must provide current weight. Must request dose that falls within the recommended dosing guidelines from the manufacturer. Reauthorization-ALGS-Approve if chart note documentation from the provider supports the condition has improved while on therapy (i.e. reduction in serum bile acids from baseline, decrease in baseline pruritis score) and the member continues to benefit from therapy. Must provide current weight. Must request dose that falls within the recommended dosing guidelines from the manufacturer. Progressive Familial Intrahepatic Cholestasis (PFIC)-Approve if member has a diagnosis of PFIC. Must provide weight and

PA Criteria	Criteria Details
	request dose that falls within the recommended dosing guidelines from the manufacturer. Must provide results of genetic testing demonstrating a gene mutation affiliated with PFIC (e.g. ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, MYO5B). Must submit labs documenting the total serum bile salt concentration above the upper limit of normal. Must provide baseline Itch Reported Outcome (ItchRO) score. Must have a documented trial with an inadequate response or significant side effect or documented contraindication to at least TWO medications for PFIC-associated pruritis (e.g. rifampicin, cholestyramine, ursodeoxycholic acid (Ursodiol). Reauthorization-PFIC-Approve if chart note documentation from the provider supports the condition has improved while on therapy (i.e. reduction in serum bile acids from baseline, decrease in baseline pruritis score) and the member continues to benefit from therapy. Must provide current weight. Must request dose that falls within the recommended dosing guidelines from the manufacturer.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

C1 ESTERASE INHIBITORS

Products Affected

- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II], Prophylaxis, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Cinryze for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating Cinryze as prophylactic therapy compared with baseline.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CABLIVI

Products Affected

- CABLIVI INJECTION KIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concurrent medications
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	Approve for 12 months
Other Criteria	aTTP-approve if the requested medication was initiated in the inpatient setting in combination with plasma exchange therapy AND patient is currently receiving at least one immunosuppressive therapy AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, histology
Age Restrictions	Thyroid carcinoma-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CALQUENCE

Products Affected

- CALQUENCE
- CALQUENCE (ACALABRUTINIB MAL)

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	Mantle Cell Lymphoma (MCL) - approve if the patient has tried at least one prior therapy. Small lymphoplasmacytic lymphoma (SLL)-approve. Chronic lymphocytic leukemia (CLL)-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CAMZYOS

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant treatment with disopyramine or ranolazine. Concomitant treatment with a beta-blocker and calcium channel blocker taken together. Concomitant treatment with moderate to strong CYP2C19 inhibitors/inducers or strong CYP3A4 inhibitors/inducers.
Required Medical Information	Diagnosis, NYHA Classification, Echocardiogram or CMR
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	12 months
Other Criteria	Symptomatic obstructive hypertrophic cardiomtopathy (HCM) - diagnosis confirmed through echocardiogram or cardiovascular magnetic resonance imaging. Patient must meet ALL of the following criteria: 1) New York Heart Association (NYHA) class II-III symptoms. 2) Left Ventricular ejection Fraction (LVEF) equals 55% or greater. 3) Left ventricular outflow track (LVOT) gradient of 50mmHg or higher. 4) Patient has a trial and failure of two of the following medications or medication classes: A) Beta-blocker, B) Calcium channel blocker, C) disopyramide
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CAPRELSA

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

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	MTC - approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CARBAGLU

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 metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	NAGS-Pt meets criteria no genetic test - 3mo. Pt had genetic test - 12mo, other-approve 7 days
Other Criteria	N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia 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

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	1 year
Other Criteria	Approve if the patient has Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	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 AND an inadequate response or intolerance to two generic antiepileptic drugs (i.e. levetiracetam, topiramate, lamotrigine) Reauth-Approve if member has been established on medication
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CEPROTIN

Products Affected

- CEPROTIN (BLUE BAR)
- CEPROTIN (GREEN BAR)

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
Coverage Duration	1 year
Other Criteria	Protein C Deficiency, Severe-approve if the patient meets the following criteria A, B and C: A) The diagnosis of protein C deficiency is confirmed by at least one of the following (i, ii, or iii): i. Plasma protein C activity below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR ii. Plasma protein C antigen below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR iii. Genetic testing demonstrating biallelic mutations in the PROC gene AND B) Acquired causes of protein C deficiency have been excluded AND C) Patient has a current or prior history of symptoms associated with severe protein C deficiency (e.g., purpura fulminans, thromboembolism).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CHEMET

Products Affected

- CHEMET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Blood lead level
Age Restrictions	Approve in patients between the age of 12 months and 18 years
Prescriber Restrictions	Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)
Coverage Duration	Approve for 2 months
Other Criteria	Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CHOLBAM

Products Affected

- CHOLBAM ORAL CAPSULE 250 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Combination Therapy with Chenodal
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with hepatologist, metabolic specialist, or GI
Coverage Duration	3 mos initial, 12 mos cont
Other Criteria	Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improvement in steatorrhea) AND does not have complete biliary obstruction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CIMZIA

Products Affected

- CIMZIA POWDER FOR RECONST
- CIMZIA STARTER KIT
- CIMZIA SUBCUTANEOUS SYRINGE KIT 400 MG/2 ML (200 MG/ML X 2)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	18 years and older for CD and PP (initial therapy), PJIA-2 years and older
Prescriber Restrictions	All dx initial therapy only. RA/AS, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist.PsA prescribed by or in consultation with a rheumatologist or dermatologist. PP, prescribed by or in consultation with a dermatologist. nr-axSpA/PJIA-prescribed by or in consultation with a rheumatologist
Coverage Duration	12 months
Other Criteria	Initial-Ankylosing Spondylitis (AS)-Approve if the patient has tried TWO of the following: an adalimumab product, Enbrel, Xeljanz/XR. Initial-Psoriatic Arthritis (PsA)-Approve if the patient has tried TWO of the following: Enbrel, an adalimumab product, Stelara, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR. PJIA/RA (Initial)-Approve if the patient has tried two of the following: Enbrel, an adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Initial-Crohn's Disease (CD)-Approve if patient has previously tried an adalimumab product. Initial-Plaque Psoriasis (PP)-Approve if the patient has tried TWO of the following: Enbrel, an adalimumab product, Skyrizi, Stelara SC, Otezla. Reauthorization-AS/PsA/RA/CD/PP-Approve if the patient had a response as determined by the prescriber. Initial-Non-radiographic axial spondylitis (nr-axSpA)-Approve if the patient 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 sacroilitis reported on MRI. Reauthorization-nr-axSpA-Approve if the patient has had a response as determined by the prescriber.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CLOBAZAM

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Lennox-Gastaut Syndrome, initial therapy-patient has tried one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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: Member must have 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 Criteria: 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

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	Authorization will be for 12 months.
Other Criteria	MTC - approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For all covered diagnoses, approve if the patient has tried Imbruvica prior to approval of Copiktra.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CORLANOR

Products Affected

- CORLANOR ORAL SOLUTION
- IVABRADINE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. One of the following: patient is on a beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate extended release) at a maximally tolerated dose, or patient has a contraindication or intolerance to beta-blocker therapy. Patient has been hospitalized for worsening HF in the previous 12 months. 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. Patient has NYHA Class II, III, or, IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide).
Age Restrictions	N/A
Prescriber Restrictions	CHF, DCM (initial): Prescribed by or in consultation with a cardiologist
Coverage Duration	CHF, DCM (initial, reauth): 12 months
Other Criteria	CHF, DCM (reauth): Documentation of positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CORTROPHIN GEL

Products Affected

- *cortrophin gel*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	MS: neurologist. RA, Psoriatic Arthritis, Ankylosing Spondylitis rheumatologist. Lupus, Dermatomyositis, Severe Psoriasis, Atopic Dermatitis: dermatologist or rheumatologist. Eye dx: ophthalmologist. Nephrotic syndrome: nephrologist. Acute Gouty Arthritis: rheumatologist, nephrologist. All other dx: no prescriber restrictions.
Coverage Duration	30 days.
Other Criteria	Initial-Multiple sclerosis (MS): must be experiencing acute exacerbation and have trial, contraindication, or intolerance of 2 IV steroids w/ inadequate response or significant side effects/toxicity. Provide rationale why corticosteroids are not expected to produce the same clinical results as expected with Purified Cortrophin Gel. For severe erythema multiforme (Stevens-Johnsons Syndrome), serum sickness, severe psoriasis, atopic dermatitis, severe acute or chronic allergic or inflammatory processes involving eye and its adnexa (e.g., allergic conjunctivitis, keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroditis, optic neuritis, chorioretinitis, anterior segment inflammation), symptomatic sarcoidosis: must have trial, contraindication, or intolerance of 2 IV steroids w/ inadequate response or significant side effects/toxicity. Provide rationale why corticosteroids are not expected to produce the same clinical results as expected with Purified Cortrophin Gel. Initial-RA (including Juvenile RA), psoriatic arthritis, ankylosing spondylitis, acute gouty arthritis: must be using as adjunctive therapy for short-term administration and have trial, contraindication, or intolerance of 2 IV steroids w/ inadequate response or significant side effects/toxicity. Provide rationale why corticosteroids are not expected to produce the same clinical results as expected with Purified

PA Criteria	Criteria Details
	Cortrophin Gel. Initial-Systemic Lupus Erythematosis (SLE), dermatomyositis (polymyositis): may be used during exacerbation or as maintenance therapy and must have trial, contraindication, or intolerance of 2 IV steroids with inadequate response or significant side effects/toxicity. Provide rationale why corticosteroids are not expected to produce the same clinical results as expected with Purified Cortrophin Gel. Reauthorization (all diagnoses): must have documentation from prescriber describing initial response to therapy and need for continuation or retreatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	Concomitant use with TNF-blocking or other biologic agent
Required Medical Information	Diagnosis
Age Restrictions	HS: 18 years and older
Prescriber Restrictions	Plaque psoriasis and Hidradentitis Supprativa (HS) - Prescribed by or in consultation with a dermatologist (initial therapy). PsA - prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). Ankylosing spondylitis, nonradiographic axial spondyloarthritis, or enthesis-related arthritis (ERA) - prescribed by or in consultation with a rheumatologist.
Coverage Duration	1 year
Other Criteria	For ankylosing spondylitis: must have active disease AND must have trial of 2 NSAIDs at target anti-inflammatory dose with inadequate responses or significant side effects/toxicity or have a contraindication. For nonradiographic axial spondyloarthritis: must have 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 AND must have trial with 2 NSAIDs with an inadeq response or signif side effects/toxicity or have a contraindication to this therapy. For PsA or ERA: must have active disease AND must have trial of 1 conventional systemic therapy (e.g., methotrexate, leflunomide, cyclosporine, sulfasalazine) with inadequate responses or significant side effects/toxicities or have contraindication to these therapies. For plaque psoriasis: must have trial of 1 conventional systemic therapy (e.g., methotrexate, acitretin, cyclosporine) with inadequate response or significant side effects/toxicity or have a contraindication OR phototherapy or photochemotherapy with inadequate response or significant side

PA Criteria	Criteria Details
	effects/toxicity or have a contraindication. For Hidradenitis Supprativa (HS): diagnosis for at least 1 year AND lesions on two distinct areas of the body AND one of the following: Hurley Stage II defined as one or more widely separated recurrent abscesses with tract information and scars or Hurley Stage III defined as multiple interconnected tracts and abscesses throughout an entire area AND a trial and failure of 90-day course of oral antibiotics for treatment of HS. For reauth: must have documentation from prescriber indicating improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Melanoma initial - must have BRAF V600 mutation.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. Histiocytic neoplasms - Approve if member will be used as a single agent.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

CUVRIOR

Products Affected

- CUVRIOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	N/A
Prescriber Restrictions	Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
Coverage Duration	1 year
Other Criteria	Member must have tried and failed penicillamine
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	1 year
Other Criteria	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

CYSTEAMINE (ORAL)

Products Affected

- CYSTAGON

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Cystagon and Procysbi
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
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	1 year
Other Criteria	Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DALFAMPRIDINE

Products Affected

- *dalfampridine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).
Coverage Duration	Initial-4months, Continuation-1 year
Other Criteria	Initial-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has impaired ambulation as evaluated by an objective measure (e.g., timed 25 foot walk and multiple sclerosis walking scale-12). Continuation-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has responded to or is benefiting from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DALIRESP

Products Affected

- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient 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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DAURISMO

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medications that will be used in combination, comorbidities
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	AML - approve if Daurismo will be used in combination with cytarabine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERASIROX

Products Affected

- *deferasirox*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DEFERIPRONE

Products Affected

- DEFERIPRONE ORAL TABLET 1,000 MG
- *deferiprone oral tablet 500 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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
- NEEDLES, INSULIN DISP.,SAFETY

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

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	Documentation of diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DIFICID

Products Affected

- DIFICID ORAL SUSPENSION FOR RECONSTITUTION
- DIFICID ORAL TABLET

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 had a trial and failure of vancomycin 125mg by mouth four times daily for 10 days and member is experiencing another infection following an initial infection episode of c. difficile or symptoms from the intial infection did not improve after initial treatment
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

DOPTELET

Products Affected

- DOPTELET (10 TAB PACK)
- DOPTELET (15 TAB PACK)
- DOPTELET (30 TAB PACK)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, platelet count, date of procedure (Thrombocytopenia with chronic liver disease)
Age Restrictions	18 years and older (for chronic ITP-initial therapy only)
Prescriber Restrictions	Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)
Coverage Duration	Thrombo w/chronic liver disease-5 days, chronic ITP-initial-3 months, cont-1 year
Other Criteria	Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 109/L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP initial-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding and must have a trial with an inadequate response or significant side effect/toxicity to ONE of the following: corticosteroids or intravenous immunoglobulin (IVIG). Continuation-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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: must have a trial of gabapentin solution with inadequate response or significant side effects/toxicity or have a contraindication to this therapy. GAD: must have a trial of sertraline concentrate with inadequate response or significant side effects/toxicity or have a contraindication to this therapy. MDD: must have a trial of fluoxetine solution with inadequate response or significant side effects/toxicity or have a contraindication to this therapy
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	COPD-Concurrent use with Ohtuvayre, Xolair, or another Anti-interleukin (IL) Monoclonal Antibody. All others-Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody.
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials. For COPD: (Initial)-Member must have a diagnosis of inadequately controlled, eosinophilic phenotype of COPD with chart note documentation and lab values taken within the previous 6 weeks or prior to starting therapy with the requested medication or another monoclonal antibody showing eosinophils greater than or equal to 300 cells per microL, FEV1/FVC ratio less than 0.7, and FEV1 of greater than or equal to 30 percent but less than or equal to 80 percent post-bronchodilator. Member must currently be treated with triple therapy (LABA/LAMA/ICS) or dual therapy (LAMA/LABA) for at least 3 months AND member has signs or symptons of chronic bronchitis for at least 3 months in the previous 12 months AND meets (A, B, C, or D): A) member experienced two or more exacerbations requiring treatment with short-acting bronchodilators and oral 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) Modified Medical Research Council (mMRC) dyspnea grade is greater than or equal to 2 or D) COPD Assessment Test (CAT) score is greater than or equal to 10. Provider attests member will continue dual or triple therapy while on requested medication. (Reauth)-Member continues to receive requested medication with dual or triple therapy combination AND 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, Esophagitis-1 year and older, Chronic Rhinosinusitis-12 years and older, COPD/PN-18 years and older
Prescriber Restrictions	Atopic Dermatitis/prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist,

PA Criteria	Criteria Details
	immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro, COPD-Prescribed by or in consultation with a pulmonologist
Coverage Duration	AD-Init-4mo, Cont-1 yr, COPD/asthma/Rhinosinusitis/esophagitis/prurigo nod-init-6 mo, cont 1 yr
Other Criteria	AD,Init-pt 2yrs and older-pt meets a and b:a.used at least 1 med,med-high,high, and/or super-high-potency rx top CS OR AD affecting ONLY face,eyes/lids,skin folds,and/or genitalia and tried tacrolimus oint AND b.Inadeq efficacy was demonstrated w/prev tx.AD,Init-pt between 6 mo and less than 2 yr-pt meets a and b:a.used at least 1 med,med-high,high, and/or super-high-potency rx top CS and b.inadeq efficacy was demonstrated w/prev tx OR AD affecting ONLY face,eyes/lids,skin folds,and/or genitalia.Cont-pt responded to Dupixent.Asthma,init-pt meets (i, ii, and iii):i.Pt meets (a or b):a)blood eosinophil greater than or equal to 150 cells per microliter w/in prev 6 wks or within 6 wks prior to tx with any IL tx or Xolair OR b)has oral CS-dependent asthma, AND ii.received combo tx w/following (a and b): a)ICS AND b)1 add asthma control/maint med(NOTE:exception to the requirement for a trial of 1 add asthma controller/maint med can be made if pt already received anti-IL-5 tx or Xolair used concomitantly w/an ICS AND iii.asthma uncontrolled or was uncontrolled prior to starting anti-IL tx or Xolair defined by 1 (a, b, c, d or e): a)exper 2 or more asthma exacer req tx with systemic CS in prev yr OR b)exper 1 or more asthma exacer requiring hosp or ED visit in prev yr OR c)FEV1 less than 80percent predicted OR d)FEV1/FVC less than 0.80 OR e)asthma worsens w/tapering of oral CS tx.Cont-pt meets (i and ii): i.cont to receive tx with 1 ICS or 1 ICS-containing combo inhaler AND ii.has responded to Dupixent.Chronic rhinosinusitis w/nasal polyposis,init-pt receiving tx with an intranasal CS and experi rhinosinusitis symptoms like nasal obstruction, rhinorrhea, or reduction/loss of smell AND meets 1 (a or b): a)received tx w/syst CS w/in prev 2 yrs or has contraindication to systemic CS tx OR b)prior surgery for nasal polyps. Cont-pt cont to receive tx with an intranasal CS and responded to Dupixent. Eosino esoph, init-weighs greater than or equal to 15 kg, has dx of eosino esophagitis confirmed by endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, and does not have a secondary cause of eosino esophagitis, and has received at least 8 wks of tx with a Rx strength PPI. Cont-pt received at least 6mo of tx with Dupixent and has experi reduced intraepithelial eosinophil count or decreased dysphagia/pain upon swallowing or reduced frequency/severity of food impaction.Prurigo Nod, init-pt has greater than or equal to 20 nodular lesions and pt has experienced pruritus at least 6 wks, AND pt tried at least 1 high- or super-high-potency Rx topical CS. Cont-pt received at least 6

PA Criteria	Criteria Details
	mo of tx with Dupixent and has experi reduced nodular lesion count, decreased pruritis or reduced nodular lesion size.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ELAPRASE

Products Affected

- ELAPRASE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
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 lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EMGALITY

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Aimovig, Vyepti or Ajovy
Required Medical Information	Diagnosis, number of migraine or cluster headaches per month, prior therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Cluster headache tx-6 months, migraine prevention-1 year
Other Criteria	Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENBREL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.
Coverage Duration	12 months
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other systemic therapy for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID), biologic or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide.Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice

PA Criteria	Criteria Details
	weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENDARI

Products Affected

- *glutamine (sickle cell)*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Oxbryta or Adakveo
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist or hematologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Initial: 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. Reauth: must have documentation from the prescriber indicating improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ENTYVIO

Products Affected

- ENTYVIO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition
Required Medical Information	N/A
Age Restrictions	CD/UC - adults (initial therapy)
Prescriber Restrictions	CD/UC initial - Prescribed by or in consultation with a gastroenterologist. (initial therapy)
Coverage Duration	CD/UC - initial 14 weeks, cont 1 year
Other Criteria	CD Initial - the patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient OR the patient has tried one conventional systemic therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, or methotrexate) OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). Note: an exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried a biologic. Cont tx - had a response to Entyvio, as determined by the prescribing physician. UC initial-the patient has had a trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone). NOTE: A trial of a biologic (e.g., an adalimumab product [e.g., Humira], an infliximab product [e.g., Remicade, Inflectra, or Renflexis], or Simponi [golimumab for SC injection]) also counts as a trial of one systemic agent for UC. Cont tx - had a response to Entyvio (for example, decreased stool frequency or rectal bleeding), as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-approve if the patient 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 patient has tried or is concomitantly receiving at least two other antiepileptics drugs. Tuberous Sclerosis Complex-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Continuation of therapy-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EPOETIN ALFA

Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	CRF anemia in patients not on dialysis.Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start.Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa, Mircera or Aranesp. Anemia w/myelosuppressive chemotx.pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start.Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp. Anemia in HIV with zidovudine, Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start.Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and pt is unwilling or unable to donate autologous blood prior to surgery
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Chemo-6m,Transfus-1m, CKD-1yr, all others-1 yr
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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERGOT ALKALOIDS

Products Affected

- *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 approval - Approve if member has diagnosis of acute migraine. Must have trials of two different formulary triptans with inadequate responses or significant side effects/toxicity unless contraindicated. Continuation of therapy - Documentation from prescriber indicating improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	BCC (La or Met) - must not have had disease progression while on Odomzo.
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Locally advanced basal cell carcinoma (LABCC), approve if 1. the patient's BCC has recurred following surgery or radiation, OR 2. the patient is not a candidate for surgery and radiation therapy. Basal cell carcinoma, metastatic-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	Authorization will be for 12 months.
Other Criteria	Advanced or Metastatic NSCLC, approve if the patient has sensitizing EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ESBRIET

Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 267 mg, 801 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	1 year
Other Criteria	IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EVEROLIMUS

Products Affected

- *everolimus (antineoplastic) oral tablet*
- *everolimus (antineoplastic) oral tablet for suspension*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Breast Cancer-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-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-Approve if member has a diagnosis of advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib. TSC-Approve if member has diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery. TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. TSC-associated partial-onset seizures-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

EVRYSDI

Products Affected

- EVRYSDI ORAL RECON SOLN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Spinal muscular atrophy (SMA) (initial): Diagnosis of spinal muscular atrophy (SMA) type I, II, or III. Both of the following: a) The mutation or deletion of genes in chromosome 5q resulting in one of the following: 1) Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) or 2) Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) AND b) Patient has at least 2 copies of SMN2. Patient is not dependent on both of the following: 1) Invasive ventilation or tracheostomy and 2) Use of non-invasive ventilation beyond use for naps and nighttime sleep. At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability: Hammersmith Infant Neurological Exam (HINE) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSE), Upper Limb Module (ULM) Test (Non ambulatory), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Motor Function Measure 32 (MFM-32) Scale, Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [item 22], Revised Upper Limb Module (RULM) test, or World Health Organization motor milestone scale. Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).
Age Restrictions	N/A
Prescriber Restrictions	SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA
Coverage Duration	Initial, Reauth: 12 months

PA Criteria	Criteria Details
Other Criteria	SMA (Reauth): Documentation of positive clinical response to therapy. Patient (Pt) continues to not be dependent on the following: use of non-invasive ventilation beyond use for naps and nighttime sleep. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FABHALTA

Products Affected

- FABHALTA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other complement inhibitor therapies (i.e empaveli, soliris, ultomiris), unresolved serious infection caused by encapsulated bacteria
Required Medical Information	Diagnosis and diagnostics listed in Other Criteria
Age Restrictions	18 years and older
Prescriber Restrictions	Precribed by or in consultation with a hematologist or nephrologist
Coverage Duration	12 months
Other Criteria	PNH (Initial)-Approve if the member meets the following A and B: A) Member has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59) via flow cytometry AND B) Member must have meningococcal vaccine at least two weeks prior to initiation of the requested medication. PNH (Reauth)-Member has experienced a positive response to treatment with the requested medication as determined by the provider. IgAN (Initial-Member must meet all the following criteria A, B, C, and D: A) Member must have a diagnosis of biopsy-proven, primary IgAN and is at risk of rapid disease progression. B) Diagnosis of IgAN is confirmed by total urine protein greater than or equal to 1 g/day AND urine protein-to-creatinine ratio is greater than or equal to 1.5 g/g. C) Attestation the member will avoid concomitant therapy with strong CYP2C8 inducers (e.g rifampin) and inhibitors (e.g. gemfibrozil) D) Must have a trial of at least 90 days with an inadequate response (defined as proteinuria greater than 1g/day OR UPCR greater than or equal to 1.5 g/g) OR member must have significant side effect/toxicity or have a contraindication to Filspari. IgAN (Reauth)-Member must have reduction in proteinuria from baseline after initial approval AND member has not experienced any treatment-restricting adverse effects (e.g., serious and life-threatening infections).
Indications	All FDA-approved Indications.

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

FABRAZYME

Products Affected

- FABRAZYME

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
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 lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient alpha-galactosidase A activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating mutations in the galactosidase alpha gene.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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 Xolair or another Anti-Interleukin (IL) Monoclonal Antibody
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	Authorization will be for 6 months initial, 12 months continuation.
Other Criteria	Initial - Must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) AND meet both of the following criteria: 1) Patient has received combination therapy with an inhaled corticosteroid AND one of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, Leukotriene receptor antagonist, or theophylline, AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted (90 percent for adolescents), OR d) Patient has an FEV1/FVC less than 0.80 (0.90 for adolescents), OR e) Patient's asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS. Continuation-The member has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased

PA Criteria	Criteria Details
	hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND patient continues to receive therapy 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 tx as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FILSPARI

Products Affected

- FILSPARI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of any of the following: Renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), aliskiren, Strong CYP3A inhibitors, Strong CYP3A inducers, Histamine H2 receptor antagonists, Proton pump inhibitors, Sensitive substrates of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), Tarpeyo
Required Medical Information	Diagnosis, lab tests as noted in other criteria
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	Initial: 6 months, Re-authorization: 12 months
Other Criteria	Initial approval-Member must meet all of the following: 1) Diagnosis of biopsy-proven, primary immunoglobulin A nephropathy (IgAN) and is at risk of rapid disease progression, 2) Diagnosis of IgAN is confirmed by all of the following: Total urine protein greater than or equal to 1 g/day, Urine protein-to-creatinine ratio is greater than or equal to 1.5 g/g, eGFR greater than or equal to 30 mL/min/1.73m2, 3) Confirmation member does not have ALT/AST greater than 3 times the upper limit of normal, 4)Confirmation Members renal function and potassium levels will be monitored frequently. Re-authorization approval-Member must meet ALL of the following: 1) Member must have reduction in proteinuria from baseline after initial approval, 2) Member has not experienced any treatment-restricting adverse effects (e.g., hepatotoxicity, acute kidney injury, severe hypotension, hyperkalemia).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FINGOLIMOD

Products Affected

- *fingolimod*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FINTEPLA

Products Affected

- FINTEPLA

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 (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FIRDAPSE

Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	History of seizures (initial therapy)
Required Medical Information	Diagnosis, seizure history, lab and test results
Age Restrictions	6 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy)
Coverage Duration	Initial-3 months, Cont-1 year
Other Criteria	Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation-patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse, according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	1 year
Other Criteria	Colon and rectal cancer-Approve if the patient meets the following (A and B): A.Patient has metastatic disease, AND B.Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GALAFOLD

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Fabry Disease (FD) (initial): Diagnosis of FD. Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. FD (initial, reauthorization): Will not be used in combination with Fabrazyme (agalsidase beta).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	FD (initial, reauth): 12 months.
Other Criteria	FD (reauthorization): Documentation of positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GATTEX

Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

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 (initial and continuation)
Coverage Duration	1 year
Other Criteria	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced improvement.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	NSCLC-approve if the patient has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Thyroid cancer - approve if the patient has advanced or metastatic rearranged during transfection (RET) fusion-positive disease, the disease is radioactive iodine-refractory AND the disease requires treatment with systemic therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC) - approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- 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	Authorization will be for 1 year
Other Criteria	Initial-Approve if the member has a diagnosis of Type II Diabetes Mellitus (T2DM) supported by any of the following: ICD-10 Code, Medical Records, Chart Notes, A1C, other lab result that confirms T2DM diagnosis. For new starts only, must have prior use of any oral diabetic medication within the past 130 days. Reauthorization-Approve if the member has been established on the requested medication and is responding positively to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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)
- LUPRON DEPOT-PED
- LUPRON DEPOT-PED (3 MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist.
Coverage Duration	uterine leiomyomata approve 3months/all other dx 12 mo
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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

HETLIOZ

Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Non-24-patient is totally blind with no perception of light
Age Restrictions	Non-24-18 years or older (initial and continuation), SMS-16 years and older
Prescriber Restrictions	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)
Coverage Duration	6 mos initial, 12 mos cont
Other Criteria	Initial-Approve if member is totally blind with no perception of light, dx 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. Cont-Approve if member is totally blind with no perception of light and pt has achieved adequate results with tasimelteon therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep). Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

HUMIRA

Products Affected

- HUMIRA PEN
- HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PSOR-UV-ADOL HS
- HUMIRA(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- HUMIRA(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	Crohn's disease (CD), 6 or older (initial therapy only). Ulcerative colitis (UC) 5 or older (initial therapy only), PP-18 or older (initial therapy only)
Prescriber Restrictions	Initial therapy only for all dx-RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV-ophthalmologist
Coverage Duration	12 months
Other Criteria	Approve Humira (NDCs starting with 00074-) Only when the member meets the following critieria - RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg,

PA Criteria	Criteria Details
	MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast cancer - Must have a trial of Verzenio or Kisqali prior to approval AND Approve recurrent or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is a premenopausal, perimenopausal, or postmenopausal woman and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Ibrance with be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant 3. Pt is a premenopausal, perimenopausal, or postmenopausal woman AND Ibrance will be used in combination with fulvestrant.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ICATIBANT

Products Affected

- *icatibant*
- *sajazir*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant - the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Philadelphia Chromosome-positive (Ph+) Acute Lymphoblastic Leukemia (ALL)-Approve if member meets one of the following A, B, 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, 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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	IDH2-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ILARIS

Products Affected

- ILARIS (PF)

PA Criteria	Criteria Details
Exclusion Criteria	When used in combination with concurrent biologic therapy (e.g.TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept.
Required Medical Information	N/A
Age Restrictions	CAPS-4 years of age and older. SJIA-2 years of age and older. Still's disease-18 years and older (Note-patients less than 18 should be referred to criteria for systemic juvenile idiopathic arthritis)
Prescriber Restrictions	CAPS/MWS/FCAS initial- Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. SJIA/Still's disease initial- prescribed by or in consultation with a rheumatologist. FMF initial - rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, hematologist. HIDS/MKD/TRAPS initial - rheumatologist, nephrologist, geneticist, oncologist, hematologist.
Coverage Duration	CAPS/SJIA-3 mos ini, 1yr cont.FMF/HIDS/MKD/TRAPS-4 mos ini, 1yr cont. Still's-3 mo ini, 1 yrcont
Other Criteria	For renewal of CAPS/MWS/FCAS/SJIA/FMF/HIDS/MKD/TRAPS/Still's - After pt had been started on Ilaris, approve if the pt had a response to therapy as determined by prescribing physician. SJIA, initial therapy - approve if the pt has tried at least one other biologic for SJIA (tocilizumab, abatacet, TNF antagonists (e.g. etanercept, adalimumab, infliximab)) or started on Ilaris while in the hospital. Adult Onset Still's Disease-Initial- approve if the patient has tried at least one other biologic or started on Ilaris while in the hospital. Acute gout flare- approve if (i and ii): (i) pt has intolerance, contraindication, or lack of response to NSAIDs and colchicine for the treatment of acute gout flares OR pt is unable to be retreated with a repeat course of corticosteroids (oral or injectable) for acute gout flare, and (ii) patient is receiving or will be taking concomitant urate lowering medication for prevention of gout unless contraindicated (ex: allopurinol, febuxostat, probenecid).
Indications	All FDA-approved Indications.

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

IMATINIB

Products Affected

- *imatinib oral tablet 100 mg, 400 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For ALL/CML, must have Ph-positive for approval of imatinib. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IMBRUVICA

Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 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	Authorization will be for 12 months.
Other Criteria	GVHD-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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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-PDGFR? 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-PDGFR? 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

IMPAVIDO

Products Affected

- IMPAVIDO

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, Sjogren-Larsson-Syndrome
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	30 Days
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	Yes

INAVOLISIB

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 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

INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- *testosterone cypionate*
- *testosterone enanthate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab results
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 therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient 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. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone 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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

INLYTA

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

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	Advanced Renal cell carcinoma-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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-approve if the patient has intermediate-2 or high-risk disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IRESSA

Products Affected

- GEFITINIB

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	NSCLC-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
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ISTURISA

Products Affected

- ISTURISA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient.
Age Restrictions	N/A
Prescriber Restrictions	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's disease (initial, reauth): 12 months
Other Criteria	Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IVERMECTIN (ORAL)

Products Affected

- *ivermectin oral*

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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

IVIG

Products Affected

- GAMMAGARD LIQUID
- GAMMAGARD S-D (IGA < 1 MCG/ML)
- OCTAGAM
- PANZYGA
- PRIVIGEN

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	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

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	1 year
Other Criteria	Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MF/PV-18 and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For polycythemia vera patients must have tried hydroxyurea. Polycythemia vera-approve if the patient has tried hydroxyurea.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	1 year
Other Criteria	Relapsed or Refractory Mantle Cell Lymphoma-Approve if the patient has tried at least one systemic regimen (i.e. rituximab, dexamethasone, cytarabine, carboplatin) AND one Bruton tyrosine kinase inhibitor (BTK inhibitor) (i.e. Brukinsa, Imbruvica, Calquence) for mantle cell lymphoma. Chronic Lymphocytic Leukemia (CLL)/Small lymphocyctic lymphoma (SLL)-Approve if patient has received at least two prior lines of therapy, including a BTK inhibitor (i.e. Brukinsa, Imbruvica, Calquence) AND a B-Cell Lymphoma inhibitor (BCL-2 inhibitor) (i.e. Venclexta).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

JOENJA

Products Affected

- JOENJA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of immunosuppressive therapy
Required Medical Information	Diagnosis, lab tests as noted in other criteria
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an immunologist or geneticist
Coverage Duration	Initial - 6 months Reauthorization - 12 months
Other Criteria	Initial criteria - Diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS) confirmed by both the following 1) Presence of an activated phosphoinositide 3-kinase delta syndrome (APDS)-associated genetic PI3K-delta mutation with a documented variant in either PIK3CD or PIK3R1 2) Submission of clinical findings and manifestations compatible with APDS (e.g., history of recurrent sinopulmonary infections, sinusitis, pneumonia, bronchitis, chronic Epstein-Barr virus and cytomegalovirus (CMV) viremia, autoimmune cytopenia, and/or lymphadenopathy/hepatomegaly) Re-authorization criteria - approve if member has experienced response to treatment as determined by prescriber
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

JUXTAPID

Products Affected

- JUXTAPID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders.
Coverage Duration	12 months
Other Criteria	Patient must have a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by the following: Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) and had clinical manifestation of HoFH before the age of 10 years OR one of the member's biological parents had untreated (LDL-C levels or total cholesterol levels consistent with HeFH OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL and had clinical manifestation of HoFH before the age of 10 years OR one of the member's biological parents had untreated LDL-C levels or total cholesterol levels consistent with HeFH, AND member must be on a high-intensity statin (e.g., atorvastatin, simvastatin) unless intolerant or contraindicated AND another LDL-lowering medication from a different class (e.g., ezetimibe, colestipol) prior to starting lomitapide.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KALYDECO

Products Affected

- KALYDECO ORAL GRANULES IN PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Orkambi, Trikafta or Symdeko
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - must have one mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KANUMA

Products Affected

- KANUMA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
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 lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient lysosomal acid lipase activity in leukocytes, fibroblasts, or liver tissue OR a molecular genetic test demonstrating lysosomal acid lipase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KERENDIA

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	Adrenal insufficiency. Concomitant treatment with strong CYP3A4 inhibitors.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	At initiation of therapy must meet all of the following: 1) estimated glomerular filtration rate (eGFR) greater than or 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. Must have an inadequate response or significant side effects/toxicity or a contraindication to the SGLT-2 inhibitor used for chronic kidney disease (e.g. Farxiga). For reauth: 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

KESIMPTA

Products Affected

- KESIMPTA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Active hepatitis B infection
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Neurologist
Coverage Duration	12 months
Other Criteria	Approved if 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 not have evidence of infection. Must not have history of progressive multifocal leukoencephalopathy (PML). Must not be on current concomitant therapy with antineoplastic, immunosuppressive or immune modulating therapies. Must have had inadequate response or intolerance to ONE of the following: dimethyl fumarate, fingolimod, teriflunomide, or glatiramer. Reauth: Must have documentation from prescriber indicating stabilization or improvement of condition
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KISQALI

Products Affected

- KISQALI FEMARA CO-PACK ORAL TABLET 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG
- 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	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast cancer (early)-Approve if member has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence AND medication will be used as adjuvant treatment in combination with an aromatase inhibitor (i.e. anastrozole, exemestane, letrozole). Breast cancer (advanced or metastatic)-Approve if member is diagnosed with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer AND medication will be used in combination with: 1) an aromatase inhibitor as initial endocrine-based therapy (i.e. anastrozole, exemestane, letrozole) OR 2) fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KORLYM

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior surgeries
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	Endogenous Cushing's Synd-1 yr.
Other Criteria	Endogenous Cushing's Syndrome-Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KOSELUGO

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: oncologist or neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

KRAZATI

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine. Colorectal Cancer (CRC)-approve if member has meets all criteria A,B, C: A) member has KRAS G12C-mutated locally advanced or metastatic CRC, 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

LAPATINIB

Products Affected

- *lapatinib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	HER2-positive recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and the patient has HR+ disease and the patient is a postmenopausal woman.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LAZERTINIB

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 Criteria: Member must have chart note documentation with diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test. Requested medication must be used in combination with amivantamab. Provider attests anticoagulant prophylaxis will be administered for the first four months of treatment. 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
Part B Prerequisite	No

LENVIMA

Products Affected

- LENVIMA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	DTC - must be refractory to radioactive iodine treatment for approval. RCC, advanced disease - approve if the pt meets i or ii:i. Lenvima is being used in combination with pembrolizumab OR ii. Lenvima is used in combination with everolimus and the patient meets the following: Patient has clear cell histology and patient has tried one antiangiogenic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. HCC-Approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIBERVANT

Products Affected

- LIBERVANT

PA Criteria	Criteria Details
Exclusion Criteria	Acute-narrow angle glaucoma
Required Medical Information	Diagnosis
Age Restrictions	Pediatrics 2 to 5 years old
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Member must have a diagnosis of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern. Member must currently be receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIVMARLI

Products Affected

- LIVMARLI ORAL SOLUTION 19 MG/ML, 9.5 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	PFIC Type 2 with specific ABCB11 variant resulting in non-functional or complete absence of bile salt export pump (BSEP) protein OR patients with prior or active hepatic decompensation events (e.g. variceal hemorrhage, ascites, hepatic encephalopathy)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	ALGS (initial): Prescribed by or in consultation with a hepatologist. PFIC: Hepatologist, gastroenterologist, or a physician who specializes Progressive Familial Intrahepatic Cholestasis (PFIC)
Coverage Duration	ALGS (initial, reauth): 12 months. PFIC-Initial-6 months Reauth-12 months
Other Criteria	Initial-Alagille Syndrome-Approve if member has a diagnosis of cholestatic pruritis associated with Alagille Syndrome. Must provide results of genetic testing confirming a JAG1 or NOTCH2 deletion or mutation. Must submit chart note documentation or labs showing two or more of the following: total serum bile acid greater than 3 times the upper limit normal (ULN) for age, conjugated bilirubin greater than 1 mg/dL, fat soluable vitamin deficiency otherwise unexplainable, GGT greater than 3 times ULN for age, intractable pruritis explainable only by liver disease. Must have trial with an inadequate response or significant side effect OR contraindication to at least TWO medications for ALGS-associated pruritis (e.g. ursodeoxycholic acid (Ursodiol), rifampin). Must provide baseline Itch Reported Outcome (ItchRO)score. Must provide current weight. Must request dose that falls within the recommended dosing guidelines from the manufacturer. Reauthorization-ALGS-Approve if chart note documentation from the provider supports the condition has improved while on therapy (i.e. reduction in serum bile acids from baseline, decrease in baseline pruritis score) and the member continues to benefit from therapy. Must provide current weight. Must request dose that falls within the

PA Criteria	Criteria Details
	recommended dosing guidelines from the manufacturer. Progressive Familial Intrahepatic Cholestasis (PFIC)-Approve if member has a diagnosis of PFIC. Must provide weight and request dose that falls within the recommended dosing guidelines from the manufacturer. Must provide results of genetic testing demonstrating a gene mutation affiliated with PFIC (e.g. ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, MYO5B). Must submit labs documenting the total serum bile salt concentration above the upper limit of normal. Must provide baseline Itch Reported Outcome (ItchRO) score. Must have a documented trial with an inadequate response or significant side effect or documented contraindication to at least ONE medication for PFIC-associated pruritis (e.g. rifampicin, cholestyramine, ursodeoxycholic acid (Ursodiol) AND Odevixibat (Bylvay). Reauthorization-PFIC-Approve if chart note documentation from the provider supports the condition has improved while on therapy (i.e. reduction in serum bile acids from baseline, decrease in baseline pruritis score) and the member continues to benefit from therapy. Must provide current weight. Must request dose that falls within the recommended dosing guidelines from the manufacturer.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis. Must have received a solid organ transplant or hematopoietic stem cell transplant. Must weigh at least 35kg. 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.
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, oncologist, infectious disease physician, or transplant physician
Coverage Duration	3 months
Other Criteria	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.
Off-Label Uses	N/A
Part B Prerequisite	No

LODOCO

Products Affected

- LODOCO

PA Criteria	Criteria Details
Exclusion Criteria	Pre-existed blood dyscrasias, renal failure, severe hepatic impairment, and concurrent use of strong CYP3A4 or P-gp inhibitors
Required Medical Information	Diagnosis, medical history of cardiovascular disease as noted in criteria
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a physician specializing in heart disease (e.g. cardiologist, lipidologist)
Coverage Duration	12 months
Other Criteria	Member has a diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD) confirmed by a history of myocardial infarction OR at least one of the following: a history of an acute coronary syndrome, stable or unstable angina, history of stroke, history of transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, member has undergone coronary or other arterial revascularization procedure in the past (e.g., coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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*
- OXYCONTIN ORAL TABLET,ORAL ONLY,EXT.REL.12 HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 60 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	Acute (ie, non-chronic) pain
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) 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.

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

LONSURF

Products Affected

- LONSURF

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	Gastric or Gastroesophageal Junction Adenocarcinoma-approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluropyrimidine, oxaliplatin and irinotecan. If the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type) they must also try Erbitux or Vectibix.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LORBRENA

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, ALK status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	NSCLC - Approve if the patient has ALK-positive metastatic NSCLC, as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LOTRONEX

Products Affected

- *alosetron*

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

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	Authorization will be for 12 months.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LUMIZYME

Products Affected

- LUMIZYME

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue OR patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

LYNPARZA

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Ovarian Cancer - Treatment-initial-Approve if the patient meets the following criteria: The patient has a germline BRCA-mutation as confirmed by an approved test. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient meets one of the following criteria (A or B): A) The patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. The patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B) The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease,

PA Criteria	Criteria Details
	has germline BRCA mutation-positive breast cancer and the patient has HER2-negative breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient meets one of the following criteria (A or B): A)metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the patient has had a bilateral orchiectomy, the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test, the patient does not have a PPP2R2A mutation and the patient has been previously treated with at least one androgen receptor directed therapy. B) germline BRCA mutation-positive metastatic disease, the medication is used in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	1 year
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	N/A
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

MEGACE

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	N/A
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

MEKINIST

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery.For NSCLC requires BRAF V600E Mutation and use in combination with Tafinlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafinlar, unless intolerant AND the patient has BRAF V600-positive disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. NSCLC-approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEMANTINE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Indication for which memantine is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MEPSEVII

Products Affected

- MEPSEVII

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
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 lysosomal storage disorders.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient beta-glucuronidase activity in leukocytes, fibroblasts, or serum OR has a molecular genetic test demonstrating glucuronidase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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

MODAFINIL/ARMODAFINIL

Products Affected

- *armodafinil*
- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD)-approve if the patient is working at least 5 overnight shifts per month. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MYALEPT

Products Affected

- MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

MYCAPSSA

Products Affected

- MYCAPSSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly. One of the following: 1) Inadequate response to surgical resection and/or pituitary irradiation, or 2) Patient is not a candidate for surgical resection or pituitary irradiation. Patient has responded to and tolerated treatment with octreotide or lanreotide.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Acromegaly (initial, reauth): 12 months
Other Criteria	Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAGLAZYME

Products Affected

- NAGLAZYME

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
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 lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating arylsulfatase B gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NAYZILAM

Products Affected

- NAYZILAM

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NERLYNX

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Stage of cancer, HER2 status, previous or current medications tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-3yrs
Other Criteria	Breast cancer, adjuvant therapy - approve if the patient meets all of the following criteria: patient will not be using this medication in combination with HER2 antagonists, patient has HER2-positive breast cancer AND Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NEXAVAR

Products Affected

- *sorafenib*

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	Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Renal cell carcinoma (RCC)-approve if the patient has relapsed or Stage IV clear cell histology and the patient has tried at least one prior systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NEXLETOL

Products Affected

- NEXLETOL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Heterozygous Familial Hypercholesterolemia (HeFH)-approve if pt meets one of the following: patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR patient has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds (a or b): a) The prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR b) The prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt is unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD) defined as: history of

PA Criteria	Criteria Details
	coronary artery disease, prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure OR at a high risk for a CVD event 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NEXLIZET

Products Affected

- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	Heterozygous Familial Hypercholesterolemia (HeFH) -approve if pt meets one of the following: has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds (a or b): a) The prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR b) The prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt is unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD) defined as: history of coronary artery disease, prior MI, history of ACS,

PA Criteria	Criteria Details
	diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure OR at a high risk for a CVD event 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NILOTINIB TARTRATE

Products Affected

- DANZITEN

PA Criteria	Criteria Details
Exclusion Criteria	Members with hypokalemia, hypomagnesemia, or long QT syndrome
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML)-Approve if in chronic phase. Chronic Phase (CP) or Accelerated Phase (AP) Ph+ CML-Approve if resistant to or intolerant to prior therapy that included imatinib. 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

NILUTAMIDE

Products Affected

- *nilutamide*

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	Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Multiple Myeloma-Approve if the member has a diagnosis of MM AND member has received at least one prior therapy for MM AND medication will used in combination with lenalidomide and dexamethasone
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NITISINONE

Products Affected

- *nitisinone*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with nitisinone products
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	Hereditary Tyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NIVESTYM

Products Affected

- NIVESTYM

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.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

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 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 of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient 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. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Indications	All FDA-approved Indications.

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

NORTHERA

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history of midodrine
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	NOH, approve if the patient meets ALL of the following criteria: a) Patient 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, AND b) Patient has tried midodrine
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if the medication is used in combination with docetaxel and the medication will be used in combination with a GnRH agonist or in combination with Firmagon or if the patient had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody.
Required Medical Information	N/A
Age Restrictions	Asthma-6 years of age and older. EGPA/Polyps-18 years of age and older. HES-12 years and older.
Prescriber Restrictions	Asthma-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist.
Coverage Duration	Initial-Asthma/EGPA/polyps-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 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

PA Criteria	Criteria Details
	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

NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NUPLAZID

Products Affected

- NUPLAZID

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	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	1 year
Other Criteria	Acute Migraine-Approve if patient has tried at least two generic triptans with inadequate responses to those therapies or the patient has a contraindication or intolerance to triptans . Episodic Migraine Prevention-Approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication and has tried at least TWO standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

NYVEPRIA

Products Affected

- NYVEPRIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	Cancer pts receiving chemo-6 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if - the 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), OR the 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 according to the prescribing physician (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
Part B Prerequisite	No

OCALIVA

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OCREVUS

Products Affected

- OCREVUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other Disease-Modifying Agents used for MS
Required Medical Information	N/A
Age Restrictions	18 years of age and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	Relapsing forms of MS-Patients new to therapy-approve if the patient had a trial with generic dimethyl fumarate prior to approval of Ocrevus. (Note: Prior treatment with Tecfidera, Bafiertam or Vumerity also counts. Also, a patient who has previously tried a glatiramer product (Copaxone, Glatopa, generic) or Lemtrada, Tysabri or Kesimpta can bypass the requirement of a trial of generic dimethyl fumarate). Continuation-approve if the patient has responded to therapy. Primary progressive MS-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist.
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. Patient has had an inadequate response to surgery and/or radiotherapy OR ii. Patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND 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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BCC - Must not have had disease progression while on Erivedge (vismodegib).
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age 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	1 year
Other Criteria	IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45 percent of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10 percent of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OGSIVEO

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. Chart documentation as noted in other criteria.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	Approve if member has a diagnosis of desmoid tumor that requires systemic treatment. Must have chart note documentation of tumor progression.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	None
Required Medical Information	Diagnosis and BRAF V600 status
Age Restrictions	Pediatrics 6 months - 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if member has relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangment, or BRAF V600 mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OJJAARA

Products Affected

- OJJAARA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis-approve if the patient has intermediate-risk or high-risk disease and the patient has anemia, defined as hemoglobin less than 10g/dL.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OLPRUVA

Products Affected

- OLPRUVA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Ravicti and Buphenyl
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	12 months
Other Criteria	Member has a confirmed diagnosis of chronic hyperammonemia due to a urea cycle disorder (UCD) amenable to treatment with sodium phenylbutyrate as verified by genetic, enzymatic or biochemical testing (submit labs confirming diagnosis)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	AML - Approve if the patient meets the following criteria (both A and B): A)Following intensive induction chemotherapy, the patient achieves one of the following according to the prescriber (i or ii): i. First complete remission OR ii. First complete remission with incomplete blood count recovery AND B) Patient is not able to complete intensive curative therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OPSUMIT

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catheterization results, WHO functional status
Age Restrictions	N/A
Prescriber Restrictions	PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OPSYNVI

Products Affected

- OPSYNVI

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, Concomitant Organic Nitrates, or Guanylate Cyclase Stimulators
Required Medical Information	Platelet and hemoglobin counts prior to initiating therapy, PAH WHO group, right heart catheterization results, WHO functional status
Age Restrictions	18 years and older
Prescriber Restrictions	Must be prescribed by or in consultation with a clinician with expertise in treating patients with pulmonary arterial hypertension
Coverage Duration	6 months (initial) 12 months (continuation)
Other Criteria	Initial: Member has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 meeting Functional Class II or III. Diagnosis has been confirmed with hemodynamic definitions obtained from a right heart catheterization (RHC) and chart notes documenting the following a, b, and c: a) mean arterial pressure (mPAP) measured greater than or equal to 20mmHg at rest b) pulmonary artery wedge pressure (PAWP) measured less than or equal to 15 mmHg c) pulmonary vascular resistance (PVR) greater than or equal to 2 woods units. Provider must attest the member does not have severe hepatic impairment or creatinine clearance 15-29 mL/min. Must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential. Member must have a trial and failure, intolerance, or contraindication to ambrisentan or bosentan OR member is established on Opsumit (macitentan) Reauth: 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

ORENCIA

Products Affected

- ORENCIA (WITH MALTOSE)
- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	N/A
Prescriber Restrictions	Initial therapy only-RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.
Coverage Duration	12 months
Other Criteria	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). PsA, initial -approve. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], initial - approve if the patient has tried one other agent for this condition or the patient will be starting on Orencia concurrently with methotrexate, sulfasalazine or leflunomide or the patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide or the patient has aggressive disease as determined by the prescribing physician. Cont tx - responded to therapy as per the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORENITRAM

Products Affected

- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT
- ORENITRAM ORAL TABLET EXTENDED RELEASE 0.125 MG
- *orenitram oral tablet extended release 0.25 mg, 1 mg, 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORILISSA

Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (EM) (initial - 150 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence. EM (200 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	EM (init, reauth-150mg): 6 mo. EM (200mg): 6 mo.
Other Criteria	EM (reauthorization - 150 mg): Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain). Treatment duration has not exceeded a total of 24 months.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORKAMBI

Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Kalydeco, Trikafta or Symdeko.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	12 months
Other Criteria	CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ORLADEYO

Products Affected

- ORLADEYO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant Use with Other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda, Takhzyro).
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Continuation-According to the prescriber the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	1 year
Other Criteria	Breast cancer in postmenopausal women or Men-approve if the patient meets the following criteria (A, B, C, D, and E): A) Patient has recurrent or metastatic disease, AND B) Patient has estrogen receptor positive (ER+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy. Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous drugs tried
Age Restrictions	Plaque Psoriasis-6 years and older- All other indications-18 years and older
Prescriber Restrictions	All dx-initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	12 months
Other Criteria	PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA initial-approve if the patient has tried at least one conventional synthetic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant (note: pts who have already tried a biologic DMARD are not required to step back and try a conventional DMARD first). Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy. PsA/PP/Behcet's- cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

OXERVATE

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	Treatment duration greater than 16 weeks per affected eye(s)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an ophthalmologist or an optometrist.
Coverage Duration	Initial-8 weeks, continuation-approve for an additional 8 weeks
Other Criteria	Patients who have already received Oxervate-approve if the patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PANRETIN

Products Affected

- PANRETIN

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, oncologist, or infectious disease specialist
Coverage Duration	1 year
Other Criteria	Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Cholangiocarcinoma-approve if the patient 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 AND the patient has been previously treated with at least one systemic therapy regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PENICILLAMINE

Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHENYLBUTYRATE

Products Affected

- PHEBURANE
- RAVICTI
- *sodium phenylbutyrate*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Ravicti and Buphenyl
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
Other Criteria	Urea cycle disorders-approve if genetic or enzymatic testing confirmed a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHEOCHROMOCYTOMA

Products Affected

- *metyrosine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication trials
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial and continuation therapy for metyrosine)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- *alyq*
- *sildenafil (pulmonary arterial hypertension) intravenous solution 10 mg/12.5 ml*
- *sildenafil (pulmonary arterial hypertension) oral tablet 20 mg*
- *tadalafil (pulmonary arterial hypertension) oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	N/A
Prescriber Restrictions	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. 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

PIMECROLIMUS (TOPICAL)

Products Affected

- *pimecrolimus*

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	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) AND generic tacrolimus (topical) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast Cancer-Approve if the patient meets the following criteria (A, B, C, D, and E): A) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND B) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND C) The patient has PIK3CA-mutated breast cancer as detected by an FDA-approved test AND D) The patient has progressed on or after an endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene) AND E) Medication will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PITOLISAN

Products Affected

- WAKIX

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh C)
Required Medical Information	Diagnosis
Age Restrictions	EDS: 6 years and older, Narcolepsy w/cataplexy: 18 years and older
Prescriber Restrictions	Must be prescribed by or in consultation with neurologist, pulmonologist, psychiatrist, or sleep specialist
Coverage Duration	12 months
Other Criteria	Initial- Narcolepsy with Cataplexy-Approve if member has a diagnosis of narcolepsy with cataplexy confirmed by submitted polysomnographic evaluation (i.e sleep study) with subsequent Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of less than 8 minutes and two or more sleep onset rapid eye movement periods (SOREMPs) including any SOREMP on the polysomnographic evaluation from the preceding night. Must provide number of cataplexy episodes at baseline. Excessive Daytime Sleepiness-Approve if member has a diagnosis of excessive daytime sleepiness associated with narcolepsy confirmed by submitted polysomnographic evaluation (i.e sleep study) with subsequent Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of less than 8 minutes and two or more sleep onset rapid eye movement periods (SOREMPs) including any SOREMP on the polysomnographic evaluation from the preceding night. For members less than 18 years of age, must have a trial and failure of modafinil. For members 18 years or older, must have a trial and failure of either modafinil or armodafinil AND a trial and failure of solriamfetol (Sunosi). Reauth-must have documentation from prescriber indicating improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	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	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	Relapsing forms of multiple scleroisis (MS)-Approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Kaposi Sarcoma/MM-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has received at least one other Revlimid (lenalidomide tablets)-containing regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

POSACONAZOLE (ORAL)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Aspergillus/Candida prophylaxis-6 months, all others-3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PREVYMIS

Products Affected

- 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. For reauth: no reauthorization is granted after initial coverage period.
Age Restrictions	N/A
Prescriber Restrictions	Hematologist, infectious disease physician, oncologist, or transplant physician
Coverage Duration	210 days
Other Criteria	Treatment duration must not exceed 200 days post-transplant.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PROLIA

Products Affected

- PROLIA

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	Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass) [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, OR 2. the patient 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, OR 3. pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR 4. the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has an osteoporotic fracture or fragility fracture . Treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer, approve if the patient has prostate cancer that is not metastatic to the bone and the patient is receiving ADT (eg, leuprolide, triptorelin, goserelin) or the patient has undergone a bilateral orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, approve if the patient has breast cancer that is not metastatic to the bone and in receiving concurrent AI therapy (eg, anastrozole, letrozole,

PA Criteria	Criteria Details
	exemestane). Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PROMACTA

Products Affected

- PROMACTA ORAL POWDER IN PACKET 12.5 MG, 25 MG
- PROMACTA 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-Hematologist or oncologist. Hepatitis C-Gastroenterologist, hematologist, hepatologist, or infectious disease specialist.
Coverage Duration	All indications-Initial-6 months Continuation-12 months
Other Criteria	Initial-First-Line Severe Aplastic Anemia (SAA)-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)-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-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 target platelet count necessary to initiate antiviral therapy and to avoid reductions in

PA Criteria	Criteria Details
	concomitant interferon-based therapy. Chronic Immune Thrombocytopenia (ITP)-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-Chronic Hepatitis C Infection-Associated Thrombocytopenia-Approve if member continues to receive interferon-based therapy. Reauthorization All Other Indications (including Chronic Hepatitis C Infection-Associated Thrombocytopenia)-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).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PYRIMETHAMINE

Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Gastrointestinal stromal tumor (GIST), advanced-approve if, the patient has two of the following imatinib, sunitinib, Sprycel or Stivarga OR if the patient has tried Ayvakit and Sprycel.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	1 year
Other Criteria	Approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication and has tried at least TWO standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RADICAVA

Products Affected

- RADICAVA
- RADICAVA ORS
- RADICAVA ORS STARTER KIT SUSP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, ALSFRS-R
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Amyotrophic lateral sclerosis (ALS) - patient must meet criteria 1 and 2: 1) Functionality retained for most activities of daily living (defined as score of 2 points or better on each individual item of the ALDFRS-R.) AND 2) Normal respiratory function confirming patient has a Forced Vital Capacity (%FVC) greater than or equal to 80% at the start of treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REMICADE

Products Affected

- REMICADE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medication, previous medications tried
Age Restrictions	CD and UC, Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy)
Prescriber Restrictions	All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA/JRA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's- rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol, cardio/neuro.
Coverage Duration	FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo
Other Criteria	RA initial, patient has tried ONE conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). CD approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other conventional systemic therapy for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection.Note-a previous trial of a biologic also counts as a trial of one other agent for CD. Ulcerative colitis (UC).Tried one systemic agent or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note-a previous trial of a biologic also counts as a trial of one systemic agent for UC. Behcet's.Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa). NOTE: An exception to the

PA Criteria	Criteria Details
	requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor for Behcet's disease. These patients who have already tried a biologic for Behcet's disease are not required to "step back" and try a conventional therapy) OR has ophthalmic manifestations. SD.Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Hidradenitis suppurativa (HS).Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried one conventional systemic treatment (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.). JIA (regardless of type of onset) approve if pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. PP- approve if the patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant or the patient has a contraindication to methotrexate (MTX), as determined by the prescriber.Note-a previous trial of a biologic also counts as a trial of a systemic agent. cont tx - approve if patient has had a response, as determined by the prescriber.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA). Sarcoidosis
Part B Prerequisite	No

REPATHA

Products Affected

- REPATHA
- REPATHA PUSHTRONEX
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Leqvio or Praluent.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
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	Approve for 1 year
Other Criteria	Hyperlipidemia with HeFH-approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: history of coronary artery disease, prior MI, history of ACS, diagnosis of angina, history of CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL (55 mg/dL for members with T2DM) or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity

PA Criteria	Criteria Details
	statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has a) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above) OR b) has baseline LDL-C 190 or greater prior to treatment with antihyperlipidemic therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RETEVMO

Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG
- 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	Authorization will be for 12 months.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has locally advanced or metastatic disease AND the tumor is RET fusion-positive. Medullary Thyroid Cancer-approve if the patient has advanced or metastatic RET-mutant disease and the disease requires treatment with systemic therapy. RET Fusion-Thyroid Cancer-approve if member has advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). RET Fusion-Positive Solid Tumors-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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REVCOVI

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab values, genetic tests (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders.
Coverage Duration	12 months
Other Criteria	ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic mutations in the ADA gene
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REVLIMID

Products Affected

- LENALIDOMIDE ORAL CAPSULE 10 MG, 15 MG, 25 MG, 5 MG
- *lenalidomide oral capsule 2.5 mg, 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and previous therapies or drug regimens tried.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Follicular lymphoma-approve if the patient is using lenalidomide (generic) in combination with rituximab or has tried at least on prior therapy. MCL - approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide (generic) in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets the following: Pt has transfusion-dependent anemia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REVUMENIB CITRATE

Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 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 diagnosis of relapsed or refractory acute leukemia AND has a lysine methyltransferase 2A gene (KMT2A) translocation as determined by an FDA approved test. 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

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	1 year
Other Criteria	Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
Age Restrictions	N/A
Prescriber Restrictions	cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients.
Coverage Duration	cGVHD (initial, reauth): 12 months
Other Criteria	cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RINVOQ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. Concurrent use with an anti-interleukin monoclonal antibody, Concurrent use with other janus kinase inhibitors, or concurrent use with Xolair.
Required Medical Information	Diagnosis, For Rinvoq LQ, 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	RA/AS/Non-Radiographic Spondy/PJIA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC/CD-prescribed by or in consultation with a gastroenterologist
Coverage Duration	12 months
Other Criteria	RA/PsA/UC/AS/CD initial-approve if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AD-approve if the patient has had a 3 month trial of at least one traditional systemic therapy or has tried at least one traditional systemic therapy but was unable to tolerate a 3 month trial. Note: Examples of traditional systemic therapies include azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Non-Radiographic Axial Spondyloarthritis-approve if the patient 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 and patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3- month trial. PJIA-Approve if member has had an inadequate response or

PA Criteria	Criteria Details
	intolerance to one or more TNF blockers (i.e. humira, enbrel) . Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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-Approve if the patient meets the following criteria (A, B, and C): A) The patient has locally advanced or metastatic solid tumor AND B) The patient's tumor has neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND C) The patient meets one of the following criteria (i or ii): i. The patient has progressed on prior therapies OR ii. There are no acceptable standard therapies and the medication is used as initial therapy. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer - Approve if the patient is in complete or partial response to platinum-based chemotherapy regimens. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy AND D) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For AML, FLT3 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	AML -approve if the patient is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SABRIL

Products Affected

- *vigabatrin*
- *vigadrone*
- *vigpoder*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Complex Partial Seizures (CPS): For use as adjunctive therapy. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SANDOSTATIN LAR

Products Affected

- *octreotide,microspheres* SUSPENSION,EXTENDED REL RECON 10 MG
- SANDOSTATIN LAR DEPOT INTRAMUSCULAR

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.Thymoma/Thymic carcinoma-prescr/consult w/oncologist
Coverage Duration	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). 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.
Off-Label Uses	Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma
Part B Prerequisite	No

SAPROPTERIN

Products Affected

- *sapropterin*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Palynziq
Required Medical Information	Diagnosis, Phe concentration
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
Coverage Duration	Initial-12 weeks, Continuation-1 year
Other Criteria	Initial-Approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy)-Approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i or ii): i. The chronic myeloid leukemia is T315I-positive, OR ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasigna (nilotinib capsules).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)
Coverage Duration	Cushing's disease/syndrome-Initial therapy - 4 months, Continuation therapy - 1 year.
Other Criteria	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Patients weighing less than 15 kg
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist
Coverage Duration	9 months
Other Criteria	Tuberculosis (Pulmonary)-Approve if the patient has diagnosis of pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampin and isoniazid and and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SKYCLARYS

Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment or advanced disease state
Required Medical Information	Genetic testing, mFARS testing, labs tests noted in clinical criteria
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist, geneticist or physician who specializes in ataxias and/or neuromuscular disorders (initial and continuation)
Coverage Duration	12 months
Other Criteria	Initial approval - member must meet ALL the following criteria: 1) Member has a diagnosis of Friedreichs ataxia as established by molecular genetic testing and detection of biallelic pathogenic variants in the FXN gene, 2) Member exhibits clinical signs and symptoms of disease that are consistent with Friedreichs ataxia, 3) Member has a baseline modified Friedreich Ataxia Rating Scale (mFARS) score between 20-80, 4) Member has a B-Type natrieuretic Peptide (BNP) that is less than or equal to 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment, 5) Prescriber attests that member does not have a history of clinically significant left-sided heart disease and/or clinically significant cardiac disease unless cardiomyopathy is associated with Friedreichs ataxia. Re-authorization approval - member must meet all the following criteria: 1) Member shows improvement of disease state as noted by an improved Friedreichs Ataxia Rating scale (mFARS) score from baseline
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SKYRIZI

Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML
- 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	PP-Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira, Cyltezo, Hyrimoz (NDCs started with 61314-)], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis)b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician.Continuation Therapy - Patient must have responded, as determined by the prescriber. Psoriatic arthritis (initial)-approve.

PA Criteria	Criteria Details
	Continuation-patient must have responded as determined by the prescriber. CD, initial-approve if the patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated or if the patient has tried one other conventional systemic therapy for CD (Please note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.) or if the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas or if the patient had ileocolonic resection (to reduce the chance of CD recurrence). Patients must be receiving an induction dosing with Skyrizi IV within 3 month of initiating therapy with Skyrizi subcutaneous. Continuation-patient must have responded as determined by the prescriber. Ulcerative Colitis-Must have moderately to severely active disease and a trial of 1 conventional therapy (e.g. corticosteroids or immunosuppressants) with inadequate response or significant side effects/toxicity unless contraindicated. Must have induction within the previous 3 months prior to initiating therapy with Skyrizi subcutaneously. For reauth: must have documentation from prescriber indicating improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOHONOS

Products Affected

- SOHONOS ORAL CAPSULE 1 MG, 1.5 MG, 10 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or orthopedist
Coverage Duration	Initial: 6 months. Re-authorization: 12 months.
Other Criteria	Initial approval - Member meets both of the following criteria: diagnosis of fidrodysplasia ossificans progressiva (FOP) and being treated to reduce the volume of new heterotopic ossification. Re-authorization criteria - Member has experienced improvement in condition as noted by one of the following: reduction, stabilization, or slowing of the rate of annualized volume of new heterotopic ossification, reduction or improvement in the signs/symptoms or number of flare-ups compared to pre-treatment levels
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOLARAZE

Products Affected

- *diclofenac sodium topical gel 3 %*

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 6 months.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOLRIAMFETOL

Products Affected

- SUNOSI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Must be prescribed by or in consultation with neurologist, pulmonologist, psychiatrist, or sleep specialist
Coverage Duration	12 months
Other Criteria	Initial-Excessive Daytime Sleepiness-Approve if member has a diagnosis of excessive daytime sleepiness associated with narcolepsy confirmed by submitted polysomnographic evaluation (i.e sleep study) with subsequent Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of less than 8 minutes and two or more sleep onset rapid eye movement periods (SOREMPs) including any SOREMP on the polysomnographic evaluation from the preceding night. Must have a trial and failure of either modafinil or armodafinil. Obstructive Sleep Apnea-Approve if member has a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea as confirmed by submitted polysomnogram evaluation (i.e sleep study). Provider must attest that underlying airway obstruction is treated (e.g. with continuous positive airway pressure (CPAP) for at least one month prior to initiating medication AND will be continued during treatment with medication. Must have a trial and failure of either modafinil or armodafinil. Reauth-must have documentation from prescriber indicating improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SOMATULINE

Products Affected

- SOMATULINE DEPOT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous treatments/therapies
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if the patient has 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). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome-approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pheochromocytoma/paraganglioma
Part B Prerequisite	No

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. patient has had an inadequate response to surgery and/or radiotherapy OR ii. The patient 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) AND patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SPRYCEL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

STELARA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	18 years and older CD/UC (initial therapy). PP-6 years and older (initial therapy).
Prescriber Restrictions	Plaque psoriasis.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-prescribed by or in consultation with a gastroenterologist (initial therapy).
Coverage Duration	12 months
Other Criteria	PP initial - Approve Stelara SC. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab) OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. CD, initial therapy (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - approve 3 months of the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.PP initial - approve Stelara SC. CD, initial therapy - approve 3 months of the SC formulation if the

PA Criteria	Criteria Details
	patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other conventional systemic therapy for CD OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For GIST, patient must have previously been treated with imatinib or Ayvakit and sunitinib or Sprycel. For HCC, patient must have previously been treated with at least one systemic regimen. Colon and Rectal cancer- approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS, the patient has tried Erbitux or Vectibix.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

SUCRAID

Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
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	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient sucrase or isomaltase activity in duodenal or jejunal biopsy specimens OR patient has a sucrose hydrogen breath test OR has a molecular genetic test demonstrating sucrose-isomaltase mutation in saliva or blood.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SUTENT

Products Affected

- *sunitinib malate*

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	Gastrointestinal stromal tumors (GIST), approve if the patient tried imatinib (Gleevec). Renal Cell Carcinoma (RCC), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or if the patient has relapsed or Stage IV disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Orkambi, Kalydeco or Trikafta
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	12 months
Other Criteria	Approve if member has diagnosis of cystic fibrosis and meets A or B: A) Must be homozygous for the F508del mutation of if the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use or B) Member has at least one mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

SYMLIN

Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

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 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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-approve. Endometriosis-approve if the patient 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 patient has previously used a gonadotropin-releasing hormone (GnRH) agonist or antagonist for endometriosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TABLOID

Products Affected

- TABLOID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Daignosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or inconsultation with, an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	Authorization will be for 12 months.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping, as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TACROLIMUS (TOPICAL)

Products Affected

- *tacrolimus topical*

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	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TADALAFIL

Products Affected

- *tadalafil oral tablet 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of nitrates.
Required Medical Information	Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
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

TAFAMIDIS

Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Onpattro or Tegsedi.Concurrent use of Vyndaqel and Vyndamax.
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
Coverage Duration	1 year
Other Criteria	Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), ii. Amyloid deposits are identified on cardiac biopsy OR iii. patient had genetic testing which, according to the prescriber, identified a TTR mutation AND Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAFINLAR

Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Initial Criteria: Approve if the member has a diagnosis of non-small cell lung cancer (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: 1) medication will be used as adjuvant therapy after tumor resection 2) disease is locally advanced, unresectable (stage III) and has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy 3) medication will be used as first-line treatment in member with metastatic disease OR 4) 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-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
Part B Prerequisite	No

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, for Breast Cancer only: BRCA mutation status, HER2 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive AND human epidermal growth factor receptor 2 (HER2) negative disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TARGRETIN TOPICAL

Products Affected

- *bexarotene topical*

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 oncologist or dermatologist (initial and continuation)
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TASIGNA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tasigna is being used. For indication of CML, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For CML, patient must have Ph-positive CML.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAVALISSE

Products Affected

- TAVALISSE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic Idiopathic Thrombocytopenic Purpura (ITP) (initial): Diagnosis of chronic immune ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL or platelet count is between 30,000/mcL and 50,000/mcl and patient is at an increased risk of bleeding. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], splenectomy, thrombopoietin receptor agonists (e.g., Nplate, Promacta), or Rituxan (rituximab) unless a patient has had a splenectomy. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding.
Age Restrictions	N/A
Prescriber Restrictions	ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	ITP (initial, reauth): 12 months
Other Criteria	ITP (reauth): Documentation of positive clinical response to therapy by confirmation of a beneficial response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAVNEOS

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: a) Granulomatosis with polyangiitis (GPA) OR b) Microscopic polyangiitis (MPA). Diagnosis is confirmed by one of the following: a) ANCA test positive for proteinase 3 (PR3) antigen or PR3 antibodies, b) ANCA test positive for myeloperoxidase (MPO) antigen or MPO antibodies, c) Tissue biopsy, or d) presence of ANCA antibodies. Patient is receiving concurrent immunosuppressant therapy with one of the following: a) cyclophosphamide, b) rituximab, c) azathioprine, or d) mycophenolate mofetil. One of the following: a) Patient is concurrently on glucocorticoids (e.g., prednisone) OR b) History of contraindication or intolerance to glucocorticoids (e.g., prednisone).
Age Restrictions	N/A
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos). Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab, mycophenolate mofetil).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAZAROTENE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TAZVERIK

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Epitheliod Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and according to the prescriber, there are no appropriate alternative therapies or the patient's tumor is positive for an EZH2 mutation and the patient has tried at least two prior systemic therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	NSCLC-approve if the patient has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations, as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TERIFLUNOMIDE

Products Affected

- TERIFLUNOMIDE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of teriflunomide with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of MS, to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TERIPARATIDE

Products Affected

- TERIPARATIDE SUBCUTANEOUS PEN INJECTOR 20 MCG/DOSE (620MCG/2.48ML)

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	2 years
Other Criteria	Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has

PA Criteria	Criteria Details
	CKD or has had an osteoporotic fracture or fragility fracture. Patients who have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TETRABENAZINE

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	For treatment of chorea associated with Huntington's disease, must be prescribed by or after consultation with a neurologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

THALOMID

Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MM - 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, IDH1 Status
Age Restrictions	All diagnoses - 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND relapsed or refractory disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TIRZEPATIDE

Products Affected

- ZEPBOUND SUBCUTANEOUS PEN INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other glucagon-like-peptide-1 (GLP-1) agonists or GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonists
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a provider specializing in sleep medicine, endocrinology, bariatrics, cardiology, or pulmonary disease
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other Criteria	Under CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOBRAMYCIN (NEBULIZATION)

Products Affected

- *tobramycin in 0.225 % nacl*
- *tobramycin inhalation*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	CF-prescr/consult w/pulm/phys specializes in tx of CF.
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cystic fibrosis-approve if the patient has pseudomonas aeruginosa in the culture of the airway.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOLVAPTAN

Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Jynarque.
Required Medical Information	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 30 days
Other Criteria	Hyponatremia - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TOPICAL RETINOID PRODUCTS

Products Affected

- *tretinoin topical*

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

TRANSDERMAL FENTANYL

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	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) 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, sickle cell disease, in hospice 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 (including transdermal fentanyl products) 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

TREMFYA

Products Affected

- TREMFYA PEN
- TREMFYA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with TNF-blocking or other biologic agent
Required Medical Information	Diagnosis
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. UC-Prescribed by or in consultation with a gastroenterologist
Coverage Duration	1 year
Other Criteria	For PsA: must have active disease AND must have trial of 1 conventional systemic therapy (e.g., methotrexate, leflunomide, cyclosporine, sulfasalazine) with inadequate responses or significant side effects/toxicities or have contraindication to these therapies. For plaque psoriasis: must have trial of 1 conventional systemic therapy (e.g., methotrexate, acitretin, cyclosporine) with inadequate response or significant side effects/toxicity or have a contraindication OR phototherapy or photochemotherapy with inadequate response or significant side effects/toxicity or have a contraindication. For reauth: must have documentation from prescriber indicating improvement in condition. For UC, must have moderately to severely active disease and a trial of 1 conventional therapy (e.g. corticosteroids or immunosuppressants) with inadequate response or significant side effects/toxicity unless contraindicated.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRIENTINE

Products Affected

- *trientine oral capsule 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history of penicillimine, pregnancy status, disease manifestations
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
Coverage Duration	Authorization will be for 1 year
Other Criteria	For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) Patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant, OR 6) the patient has been started on therapy with trientine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

TRIKAFTA

Products Affected

- TRIKAFTA ORAL TABLETS, SEQUENTIAL

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.
Required Medical Information	Diagnosis, specific CFTR gene mutations, concurrent medications
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	12 months
Other Criteria	CF - must have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TRUQAP

Products Affected

- TRUQAP

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	1 year
Other Criteria	Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TUKYSA

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Breast Cancer-approve if the patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-positive disease, Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type), AND Patient has been previously treated with a fluoropyrimidine, AND oxaliplatin, AND irinotecan.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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 (Pigmented Villonodular Synovitis)- approve if, according to the prescriber, the tumor is not amenable to improvement with surgery.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TYSABRI

Products Affected

- TYSABRI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agents used for MS. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) in Crohn's disease (CD) patients.
Required Medical Information	Diagnosis
Age Restrictions	Adults (initial and continuation)
Prescriber Restrictions	MS. Prescribed by, or in consultation with, a neurologist or physician who specializes in the treatment of MS (initial and continuation). CD. Prescribed by or in consultation with a gastroenterologist (initial and continuation).
Coverage Duration	MS-Authorization will be for 1 year .CD, initial-6 mo. CD, cont therapy-1 year.
Other Criteria	Adults with a relapsing form of MS-initial. Approve if the patient is new to therapy and has had a trial of generic dimethyl fumarate (prior treatment with Tecfidera, Bafiertam or Vumerity also counts. Also, a patient who has previously tried a glatiramer product (Copaxone, Glatopa, generic) can bypass the requirement of a trial of generic dimethyl fumarate) OR approve if the patient has highly active or aggressive multiple sclerosis by meeting one of the following: a) rapidly advancing deterioration in physical functioning Note: examples include loss of mobility/or lower levels of ambulation, severe changes in strength or coordination, b) disabling relapse with suboptimal response to systemic corticosteroids, c) magnetic resonance imaging (MRI) findings suggest highly active or aggressive multiple sclerosis Note: Examples include new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions, or d) manifestations of multiple sclerosis-related cognitive impairment OR patient has previously received one of the following therapies: Lemtrada, Ocrevus, or Kesimpta.Continuation-approve if the patient has had a response to Tysabri.Adults with CD, initial. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein) and patient has tried two of the following agents for CD for at least 2 months

PA Criteria	Criteria Details
	each: adalimumab, certolizumab pegol, infliximab, vedolizumab, ustekinzumab, OR pt has had an inadequate response or was intolerant to these agents. CD, continuation therapy. Patient has had a response to Tysabri, as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

TYVASO

Products Affected

- TYVASO DPI INHALATION CARTRIDGE WITH INHALER 16 MCG, 16(112)-32(112) -48(28) MCG, 32 MCG, 48 MCG, 64 MCG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PAH/PAH associated with ILD (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH/PAH associated with ILD: Initial: 6 months. Reauth: 12 months.
Other Criteria	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. PAH (Reauth): Documentation of positive clinical response to therapy. PAH associated with Interstitial lung disease (ILD) (initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH AND diagnosis of ILD is confirmed by high-resolution computed tomography. PAH associated with ILD (reauth): Documentation of positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

UPTRAVI

Products Affected

- UPTRAVI ORAL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Confirmation of right heart catheterization, medication history of current use or previous use of one of the following: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], Adempas, prostacyclin therapy (eg, Orenitram, Ventavis, or epoprostenol injection)
Age Restrictions	N/A
Prescriber Restrictions	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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

VALTOCO

Products Affected

- VALTOCO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VANFLYTA

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test and this medication is being used for induction, consolidation, or maintenance treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VEMLIDY

Products Affected

- VEMLIDY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist, hepatologist, transplant physician, or infectious disease physician
Coverage Duration	12 months
Other Criteria	Initial-Approve if member has diagnosis of chronic hepatitis B confirmed by ALL of the following: HBsAg positive or negative for at least 6 months, documented evidence of active viral replication (HBeAg+ and HBV DNA greater than 100,000 copies per mL), 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 of entecavir and tenofovir disoproxil fumarate with inadequate response or significant side effects OR have a contraindication to these therapies. Reauthorization-Approve if documentation provided indicates continued benefit from treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VENCLEXTA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	AML-approve if the patient is using Venclexta in combination with either azacitidine, decitabine, or cytarabine. In addition, for all covered diagnoses (except AML), approve if the patient has tried Imbruvica prior to approval of Venclexta.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Breast Cancer, Early-Approve if pt meets (A, B, and C): A)Pt has HR+ and HER2-negative disease, AND B) Pt has node-positive disease at high risk of recurrence (Note-High risk includes patients 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 C) Medication be used in combo with endocrine therapy (tamoxifen or an aromatase inhibitor). Breast Cancer, Advanced or Metastatic-Approve if pt has HR+ and HER2-negative breast cancer AND medication will be used in combo with an aromatase inhibitor as initial endocrine-based therapy (i.e. anastrozole, exemestane, or letrozole). Breast Cancer, Advanced or Metastatic (no prior chemotherapy)-Approve if pt has HR+ and HER2-negative breast cancer with disease progression following endocrine therapy AND the medication will be used in combination with fulvestrant. Breast Cancer, Advanced or Metastatic (after chemotherapy)-Approve if pt has HR+ and HER2-negative breast cancer following endocrine therapy AND prior chemotherapy in the metastatic setting AND medication will be used as monotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

VIBERZI

Products Affected

- VIBERZI

PA Criteria	Criteria Details
Exclusion Criteria	Lack of gallbladder. Known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction. Alcoholism, alcohol abuse, alcohol addiciton, or drink more than 3 alcoholic beverages/day. History of pancreatitis, structural diseases of the pancreas, including known or suspected pancreateic duct obstruction. severe hepatic impairment. history of chronic or severe constipation or sequale from constipation, or known or suspected mechanical gastrointestinal obstruction.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with gastroenterologist
Coverage Duration	6 months (initial) 12 months (reauth)
Other Criteria	Diarrhea-predominant irritable bowel syndrome (IBS-D) that has persisted for 6 months or longer AND a history of failure, contraindication or intolerance to two of the following antispasmodics (e.g. dicyclomine), antidiarrheal (e.g. diphenoxylate/atropine), or tricyclic antidepressants (e.g. amitriptyline) Reauth - documentation from prescriber indicating improvement in condition
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VIJOICE

Products Affected

- VIJOICE ORAL GRANULES IN PACKET
- VIJOICE ORAL TABLET 125 MG, 250 MG/DAY (200 MG X1-50 MG X1), 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, PIK3CA gene mutation
Age Restrictions	2 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	PIK3CA-Related Overgrowth Spectrum - patient has at least one target lesion identified on imaging
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VIMIZIM

Products Affected

- VIMIZIM

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	N/A
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 lysosomal storage disorders.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine-6-sulfatase activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating N-acetylgalactosamine-6-sulfatase gene mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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, NTRK gene fusion status
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Solid tumors - approve if the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity AND there are no satisfactory alternative treatments or the patient has disease progression following treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, EGFR status, exon deletions or substitutions
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VONJO

Products Affected

- VONJO

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-approve if the patient has intermediate risk or high risk disease and the patient has a platelet count of less than 50 X 10 9/L (less than 50,000/mcL)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VORASIDENIB

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 Months
Other Criteria	Initial Criteria: Member must have a grade 2 astrocytoma or oligodendroglioma with susceptible IDH1 or IDH2 mutation, as detected by an approved test, following surgery including biopsy, sub-total resection, or gross total resection with chart note documentation. 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 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
Part B Prerequisite	No

VORICONAZOLE (ORAL)

Products Affected

- *voriconazole oral suspension for reconstitution*
- *voriconazole oral tablet 200 mg, 50 mg*

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

VOSEVI

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
Age Restrictions	18 years or older
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

VOTRIENT

Products Affected

- *pazopanib*
- VOTRIENT

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	Soft tissue sarcoma other than GIST [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], approve. Advanced Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or stage IV disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

VOWST

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis. Must have documentation of a stool test positive for toxigenic Clostridioides difficile. Must have a trial of both bezlotoxumab and fecal microbiota, live-jslm with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies.
Age Restrictions	N/A
Prescriber Restrictions	Gastroenterologist or infectious disease specialist
Coverage Duration	30 days
Other Criteria	Reauthorization is subject to all initial criteria and requires chart note documentation describing the previous response and clinical rationale for retreatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Approve if the patient is new to therapy and if the patient has tried a generic MS disease modifying agent. Note: Prior use of brand Tecfidera, Bafiertam, Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

WEGOVY

Products Affected

- WEGOVY SUBCUTANEOUS PEN INJECTOR 0.25 MG/0.5 ML, 0.5 MG/0.5 ML, 1 MG/0.5 ML, 1.7 MG/0.75 ML, 2.4 MG/0.75 ML

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	Initial-6 months Reauth-12 months
Other Criteria	Initial-Must be used in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular (CV) events in members with established CV disease. Must be either obese or overweight defined as having a BMI greater than or equal to 27 kg per m2 upon inital request. Chart note documentation must include baseline body weight and calculated BMI. Must have established CV disease defined by one of the following: previous myocardial infarction, ischemic or hemorrhagic stroke, or symptomatic peripheral arterial disease (PAD). Provider must attest the member has a plan for reduced-calorie diet and increased physical activity and has been evaluated for co-morbid conditions that increase the risk of CV disease. Provider must indicate if the member has one of the following: dyslipidemia, heart failure (HF), chronic kidney disease (CKD), or type 2 diabetes mellitus (T2DM) and provide attestation that members with co-morbities will be treated (as determined by the prescriber). Must provide clinical rationale for use of semaglutide (Wegovy) instead of semaglutide (Ozempic) that includes why semaglutide (Ozempic) is not producing a sufficient risk reduction and why semaglutide (Wegovy), the same chemical, is expected to produce a better risk reduction. Reauth-Approve if the member has responded positively to therapy as determined by the prescribing physician, the member continues to follow the plan for reduced-calorie diet and

PA Criteria	Criteria Details
	increased physical activity, and attestation that members with co-morbities will continue to be treated as determined by the prescriber
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

WELIREG

Products Affected

- WELIREG

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- approve if pt has advanced disease AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

WINREVAIR

Products Affected

- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Platelet and hemoglobin counts prior to initiating therapy, PAH WHO group, right heart catheterization results
Age Restrictions	18 years and older
Prescriber Restrictions	Must be prescribed by or in consultation with a clinician with expertise in treating patients with pulmonary arterial hypertension
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	Initial: Member must have a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1. Diagnosis has been confirmed with hemodynamic definitions obtained from a right heart catheterization (RHC) and chart notes documenting the following a, b, and c: a) mean arterial pressure (mPAP) measured greater than or equal to 20mmHg at rest b) pulmonary artery wedge pressure (PAWP) measured less than or equal to 15 mmHg c) pulmonary vascular resistance (PVR) greater than or equal to 2 woods units. Member must be established, have a contraindication, or an intolerance to at least two medications from the following drug classes: Phosphodiesterase Type-5 Inhibitor, Endothelin Receptor Antagonist, Soluble cGMP Stimulator, or Prostacyclin Receptor Agonist. Must have baseline negative pregnancy test prior to initiation of therapy if a natal female of reproductive potential and platelet counts are greater than 50,000/mm3 prior to initiation of therapy and will be discontinued if dropped to less than 50,000/mm3. 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

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	Anaplastic large cell lymphoma-patients greater than or equal to 1 year of age. Inflammatory Myofibroblastic Tumor - 1 year of age and older. All other diagnoses -18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test or ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND has received at least one prior systemic treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XDEMVY

Products Affected

- XDEMVY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 weeks
Other Criteria	Approve if the member has a diagnosis of blepharitis due to Demodex infestation confirmed by the presence of all the following in at least one (1) eye: 1) Demodex infestations with greater than 10 lashes with collarettes present on the upper lid (collarette scale grade 2 or worse), 2) mild erythema of the upper eyelid margin, 3) average mite density of greater than 1.5 mites per lash (upper and lower eyelids combined).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XELJANZ

Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	AS/PsA/RA/UC-18 years and older (initial therapy)
Prescriber Restrictions	RA, JIA/JRA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist.
Coverage Duration	12 months
Other Criteria	RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial and the requested medication will be used in combination with methotrexate or another conventional synthetic disease modifying antirheumatic drug (DMARD), unless contraindicated. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least

PA Criteria	Criteria Details
	one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XERMELO

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XIAFLEX

Products Affected

- XIAFLEX

PA Criteria	Criteria Details
Exclusion Criteria	Retreatment (i.e., treatment beyond three injections per affected cord for those with Dupuytren's Contracture or beyond eight injections for Peyronie's Disease).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Dupuytren's Contracture-administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Peyronie's Disease -administered by a healthcare provider experienced in the treatment of male urological diseases.
Coverage Duration	Dupuytren's Contracture-3 months, Peyronie's Disease-6 months
Other Criteria	Dupuytren's Contracture-at baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees AND the patient will not be treated with more than a total of three injections (maximum) per affected cord. Peyronie's Disease-the patient meets ONE of the following (i or ii): i. at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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	Must be age 12 or older for Travelers Diarrhea, Age 18 or older for Hepatic encephalopathy prophylaxis and IBS-D
Prescriber Restrictions	N/A
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. Initial-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. Initial-Hepatic encephalopathy (HE)-Approve if member has diagnosis of HE. Must have previous treatment, intolerance or contraindication of lactulose. Reauthorization-HE-Provider attests the member has benefitted from the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No

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 an Interleukin (IL) Antagonist Monoclonal Antibody or Palforzia (peanut allergen powder)
Required Medical Information	Moderate to severe persistent asthma, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline 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 the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine).
Age Restrictions	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older.
Prescriber Restrictions	Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist. Food allergy- allergist or immunologist
Coverage Duration	asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months, Food allergy-1 yr
Other Criteria	Initial-Moderate to severe persistent asthma-Approve if pt meets criteria 1 and 2: 1) pt 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 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy 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 OR b) The

PA Criteria	Criteria Details
	patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80 percent predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician. Nasal Polyps Initial-Approve if the patient has a baseline IgE level greater than or equal to 30 IU/ml, patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell and patient is currently receiving therapy with an intranasal corticosteroid. Nasal polyps continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy. IgE-Mediated Food Allergy-approve if pt meets (A, B, C and D): (A) baseline IgE greater than or equal to 30 IU/mL, and (B) positive skin prick test to one or more foods and positive in vitro test for IgE to one or more foods, and (C) history of allergic reaction that met all of the following: pt demonstrated signs and symptoms of a significant systemic allergic reaction, and reaction occurred within a short period of time following a known ingestion of the food, and prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, and (D) pt has been prescribed an epinephrine auto-injector.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, FLT3-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XPOVIO

Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 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), 80MG TWICE WEEK (160 MG/WEEK)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib. Diffuse large B-cell lymphoma-approve if the patient has been treated with at least two prior systemic therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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 for which Xtandi is being used.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.]
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XYREM

Products Affected

- SODIUM OXYBATE

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Xywav, Wakix, Sunosi
Required Medical Information	Medication history of CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by a sleep specialist physician or a Neurologist
Coverage Duration	12 months.
Other Criteria	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil (for members 18 years of age and older only) and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

XYWAV

Products Affected

- XYWAV

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of sedatives, concomitant use of alcohol, succinic semialdehyde dehydrogenase deficiency
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by or in consultation with neurologist, psychiatrist, or sleep specialist
Coverage Duration	12 months
Other Criteria	Initial-Narcolepsy with Cataplexy-Approve if member has a diagnosis of narcolepsy with cataplexy confirmed by submitted polysomnographic evaluation (i.e sleep study) with subsequent Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of less than 8 minutes and two or more sleep onset rapid eye movement periods (SOREMPs) including any SOREMP on the polysomnographic evaluation from the preceding night. Must provide history of cataplexy episodes. Must have a trial and failure of sodium oxybate. Excessive Daytime Sleepiness-Approve if member has a diagnosis of excessive daytime sleepiness associated with narcolepsy confirmed by submitted polysomnographic evaluation (i.e sleep study) with subsequent Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of less than 8 minutes and two or more sleep onset rapid eye movement periods (SOREMPs) including any SOREMP on the polysomnographic evaluation from the preceding night. Must have a trial and failure of solriamfetrol (Sunosi) AND pitolisant (Wakix), unless both of these therapies are not FDA-approved or compendia supported for use in the member's age. Must provide baseline Epworth Sleepiness Scale (ESS). Idiopathic Hypersomnia-Approve if member has a diagnosis of idiopathic hypersomnia as confirmed by using ICSD-3 criteria with submitted polysomnography and MSLT showing: member has less than 2 sleep onset rapid eye movement periods (SOREMPs) OR has no SOREMPs if the REM sleep latency on the preceding nocturnal polysomnogram (PSG) was

PA Criteria	Criteria Details
	less than or equal to 15 minutes, mean sleep latency of less than or equal to 8 minutes OR total 24-hour sleep time greater than or equal to 660 minutes (typically 12 to 14 hours) on 24-hour polysomnography monitoring or by wrist actigraphy in association with a sleep log, insufficient sleep syndrome has been ruled out, and the hypersomnolence and/or MSLT findings are not better explained by another sleep disorder, other medical or psychiatric disorder, or use of drugs or medications. Must provide baseline Epworth Sleepiness Scale (ESS) that is greater than or equal to 10. Must have absence of cataplexy. Reauthorization (all conditions)-Must have documentation from prescriber indicating improvement in condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

YONSA

Products Affected

- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concomitant medications
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Metastatic castration-resistant prostate cancer (mCRPC) - approve if the patient will be using Yonsa in combination with methylprednisolone and the patient meets ONE of the following criteria (i or ii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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

ZEJULA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after first-line platinum-based chemotherapy regimen. Deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - - approve if the patient is in complete or partial response after first-line platinum-based chemotherapy regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BRAFV600 mutation status required.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. Erdheim-Chester disease, in patients with the BRAF V600 mutation-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	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	1 year
Other Criteria	MS, initial treatment-approve if the patient 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, initial-approve if the patient has tried an adalimumab product (a trial of Simponi SC or infliximab would also count). Cont tx-approve if the patient has been established on Zeposia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZIEXTENZO

Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	Cancer pts receiving chemo-6 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if-the 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), OR the 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 according to the prescribing physician (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
Part B Prerequisite	No

ZOLINZA

Products Affected

- ZOLINZA

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 including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with strong CYP450 inducers
Required Medical Information	Genetic tests for cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist
Coverage Duration	Initial: 6 months. Re-authorization: 12 months.
Other Criteria	Initial Approval-Member must meet ALL of the following: 1) diagnosis of CDD confirmed by genetic testing, 2) member must be refractory to at least TWO antiepileptic drugs, 3) member will be monitored for the emergence or worsening of depression, suicidal thoughts/behavior, unusual changes in mood or behavior. Re-Authorization approval-member must meet ALL of the following: 1) Member must meet initial criteria, 2) Member must have demonstrated a positive clinical response to Ztalmy therapy, 3) member must be absent of unacceptable toxicity from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZURZUVAE

Products Affected

- ZURZUVAE

PA Criteria	Criteria Details
Exclusion Criteria	Previous treatment with Zurzuvae 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	Postpartum depression-approve if the patient meets the following (A, B and C): A.Patient meets BOTH of the following (i and ii): i. Patient has been diagnosed with severe depression, AND ii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery, AND B. Patient is less than or equal to 12 months postpartum, AND C. Patient is not currently pregnant.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYDELIG

Products Affected

- ZYDELIG

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 all covered diagnoses-approve if the patient has tried Imbruvica prior to approval of Zydelig.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYKADIA

Products Affected

- ZYKADIA

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	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

ZYTIGA

Products Affected

- *abiraterone oral tablet 250 mg, 500 mg*

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	Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, or the medication is concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)-approve if the medication is used in combination with prednisone and the medication is concurrently used with a gonadotropin-releasing hormone agonist or concurrently used with Firmagon or the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PART B VERSUS PART D

Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- ABRAXANE INTRAVENOUS SUSPENSION FOR RECONSTITUTION 100 MG
- *acetylcysteine solution 100 mg/ml (10 %), 200 mg/ml (20 %)*
- *acyclovir sodium intravenous solution 50 mg/ml*
- ADCETRIS INTRAVENOUS RECON SOLN 50 MG
- *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*
- ALIMTA INTRAVENOUS RECON SOLN 100 MG, 500 MG
- ALIQOPA INTRAVENOUS RECON SOLN 60 MG
- *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*
- *arsenic trioxide intravenous solution 1 mg/ml, 2 mg/ml*
- ASPARLAS INTRAVENOUS SOLUTION 750 UNIT/ML
- *azacitidine injection recon soln 100 mg*
- *azathioprine oral tablet 50 mg*
- *azathioprine sodium injection recon soln 100 mg*
- BAVENCIO INTRAVENOUS SOLUTION 20 MG/ML
- BELEODAQ INTRAVENOUS RECON SOLN 500 MG
- BENDEKA INTRAVENOUS SOLUTION 25 MG/ML
- BESPONSA INTRAVENOUS RECON SOLN 0.9 MG (0.25 MG/ML INITIAL)
- BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG
- *bortezomib injection recon soln 3.5 mg*
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- *busulfan intravenous solution 60 mg/10 ml*
- *carboplatin intravenous solution 10 mg/ml*
- *carmustine intravenous recon soln 100 mg*
- *cisplatin intravenous solution 1 mg/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 %
- CLINIMIX 6%-D5W (SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 6-5 %
- CLINIMIX 8%-D10W(SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 8-10 %
- CLINIMIX 8%-D14W(SULFITE-FREE) INTRAVENOUS PARENTERAL SOLUTION 8-14 %
- *clofarabine intravenous solution 1 mg/ml*
- *cromolyn inhalation solution for nebulization 20 mg/2 ml*
- *cyclophosphamide intravenous recon soln 1 gram, 2 gram, 500 mg*
- *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*
- *dacarbazine intravenous recon soln 100 mg, 200 mg*
- *dactinomycin intravenous recon soln 0.5 mg*
- DANYELZA INTRAVENOUS SOLUTION 4 MG/ML
- DARZALEX INTRAVENOUS SOLUTION 20 MG/ML
- *daunorubicin intravenous solution 5 mg/ml*
- *decitabine intravenous recon soln 50 mg*
- *deferoxamine injection recon soln 2 gram, 500 mg*
- *dexrazoxane hcl intravenous recon soln 250 mg, 500 mg*
- *docetaxel intravenous solution 160 mg/16 ml (10 mg/ml), 160 mg/8 ml (20 mg/ml), 20 mg/2 ml (10 mg/ml), 20 mg/ml (1 ml), 80 mg/4 ml (20 mg/ml), 80 mg/8 ml (10 mg/ml)*
- *doxorubicin intravenous recon soln 10 mg, 50 mg*
- *doxorubicin intravenous solution 10 mg/5 ml, 2 mg/ml, 20 mg/10 ml, 50 mg/25 ml*
- *doxorubicin, peg-liposomal intravenous suspension 2 mg/ml*
- *dronabinol oral capsule 10 mg, 2.5 mg, 5 mg*
- ELZONRIS INTRAVENOUS SOLUTION 1,000 MCG/ML
- EMEND ORAL SUSPENSION FOR RECONSTITUTION 125 MG (25 MG/ ML FINAL CONC.)
- 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
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HR 0.75 MG, 1 MG, 4 MG
- *epirubicin intravenous solution 200 mg/100 ml*
- ERBITUX INTRAVENOUS SOLUTION 100 MG/50 ML, 200 MG/100 ML
- ERWINASE INJECTION RECON SOLN 10,000 UNIT
- ETOPOPHOS INTRAVENOUS RECON SOLN 100 MG
- *etoposide intravenous solution 20 mg/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
- *fludarabine intravenous recon soln 50 mg*
- *fludarabine intravenous solution 50 mg/2 ml*
- FOLOTYN INTRAVENOUS SOLUTION 20 MG/ML (1 ML), 40 MG/2 ML (20 MG/ML)
- *formoterol fumarate inhalation solution for nebulization 20 mcg/2 ml*
- *fulvestrant intramuscular syringe 250 mg/5 ml*
- GAZYVA INTRAVENOUS SOLUTION 1,000 MG/40 ML
- *gemcitabine intravenous recon soln 1 gram, 2 gram, 200 mg*
- *gemcitabine intravenous solution 1 gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml (38 mg/ml), 200 mg/5.26 ml (38 mg/ml)*
- GEMCITABINE INTRAVENOUS SOLUTION 100 MG/ML
- *gengraf oral capsule 100 mg, 25 mg*
- *gengraf oral solution 100 mg/ml*
- *granisetron hcl oral tablet 1 mg*
- HALAVEN INTRAVENOUS SOLUTION 1 MG/2 ML (0.5 MG/ML)
- HEPLISAV-B (PF) INTRAMUSCULAR SYRINGE 20 MCG/0.5 ML
- HIZENTRA SUBCUTANEOUS SOLUTION 1 GRAM/5 ML (20 %), 10

GRAM/50 ML (20 %), 2 GRAM/10 ML (20 %), 4 GRAM/20 ML (20 %)
- HIZENTRA SUBCUTANEOUS SYRINGE 1 GRAM/5 ML (20 %), 10 GRAM/50 ML (20 %), 2 GRAM/10 ML (20 %), 4 GRAM/20 ML (20 %)
- HYQVIA SUBCUTANEOUS SOLUTION 10 GRAM /100 ML (10 %), 2.5 GRAM /25 ML (10 %), 20 GRAM /200 ML (10 %), 30 GRAM /300 ML (10 %), 5 GRAM /50 ML (10 %)
- *idarubicin intravenous solution 1 mg/ml*
- *ifosfamide intravenous recon soln 1 gram, 3 gram*
- *ifosfamide intravenous solution 1 gram/20 ml, 3 gram/60 ml*
- IMFINZI INTRAVENOUS SOLUTION 50 MG/ML
- *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*
- *irinotecan intravenous solution 100 mg/5 ml, 300 mg/15 ml, 40 mg/2 ml, 500 mg/25 ml*
- ISTODAX INTRAVENOUS RECON SOLN 10 MG/2 ML
- IXEMPRA INTRAVENOUS RECON SOLN 15 MG, 45 MG
- JEMPERLI INTRAVENOUS SOLUTION 50 MG/ML
- JEVTANA INTRAVENOUS SOLUTION 10 MG/ML (FIRST DILUTION)
- JYLAMVO ORAL SOLUTION 2 MG/ML
- KADCYLA INTRAVENOUS RECON SOLN 100 MG, 160 MG
- KEYTRUDA INTRAVENOUS SOLUTION 25 MG/ML
- KHAPZORY INTRAVENOUS RECON SOLN 175 MG
- KIMMTRAK INTRAVENOUS SOLUTION 100 MCG/0.5 ML
- KYPROLIS INTRAVENOUS RECON SOLN 10 MG, 30 MG, 60 MG
- *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*
- *levoleucovorin calcium intravenous recon soln 50 mg*
- *levoleucovorin calcium intravenous solution 10 mg/ml*
- LIBTAYO INTRAVENOUS SOLUTION 50 MG/ML
- MARGENZA INTRAVENOUS SOLUTION 25 MG/ML
- *melphalan hcl intravenous recon soln 50 mg*
- *mesna intravenous solution 100 mg/ml*
- *methotrexate sodium (pf) injection recon soln 1 gram*
- *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*
- *mitomycin intravenous recon soln 20 mg, 40 mg, 5 mg*
- *mitoxantrone intravenous concentrate 2 mg/ml*
- MONJUVI INTRAVENOUS RECON SOLN 200 MG
- MOZOBIL SUBCUTANEOUS SOLUTION 24 MG/1.2 ML (20 MG/ML)
- *mycophenolate mofetil (hcl) intravenous recon soln 500 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*
- MYLOTARG INTRAVENOUS RECON SOLN 4.5 MG (1 MG/ML INITIAL CONC)

- *nelarabine intravenous solution 250 mg/50 ml*
- NULOJIX INTRAVENOUS RECON SOLN 250 MG
- ONCASPAR INJECTION SOLUTION 750 UNIT/ML
- *ondansetron hcl oral solution 4 mg/5 ml*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet,disintegrating 4 mg, 8 mg*
- ONIVYDE INTRAVENOUS DISPERSION 4.3 MG/ML
- OPDIVO INTRAVENOUS SOLUTION 100 MG/10 ML, 120 MG/12 ML, 240 MG/24 ML, 40 MG/4 ML
- *oxaliplatin intravenous recon soln 100 mg, 50 mg*
- *oxaliplatin intravenous solution 100 mg/20 ml, 200 mg/40 ml, 50 mg/10 ml (5 mg/ml)*
- *paclitaxel intravenous concentrate 6 mg/ml*
- PADCEV INTRAVENOUS RECON SOLN 20 MG, 30 MG
- *paraplatin intravenous solution 10 mg/ml*
- *pentamidine inhalation recon soln 300 mg*
- PERJETA INTRAVENOUS SOLUTION 420 MG/14 ML (30 MG/ML)
- PLENAMINE INTRAVENOUS PARENTERAL SOLUTION 15 %
- POLIVY INTRAVENOUS RECON SOLN 140 MG, 30 MG
- POTELIGEO INTRAVENOUS SOLUTION 4 MG/ML
- *premasol 10 % intravenous parenteral solution 10 %*
- PROGRAF INTRAVENOUS SOLUTION 5 MG/ML
- PROGRAF ORAL GRANULES IN PACKET 0.2 MG, 1 MG
- PULMOZYME INHALATION SOLUTION 1 MG/ML
- 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
- *romidepsin intravenous recon soln 10 mg/2 ml*
- RUXIENCE INTRAVENOUS SOLUTION 10 MG/ML
- RYBREVANT INTRAVENOUS SOLUTION 50 MG/ML
- RYLAZE INTRAMUSCULAR SOLUTION 10 MG/0.5 ML
- SARCLISA INTRAVENOUS SOLUTION 20 MG/ML
- SIMULECT INTRAVENOUS RECON SOLN 10 MG, 20 MG
- *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*
- TECENTRIQ INTRAVENOUS SOLUTION 1,200 MG/20 ML (60 MG/ML), 840 MG/14 ML (60 MG/ML)
- TEMODAR INTRAVENOUS RECON SOLN 100 MG
- *temsirolimus intravenous recon soln 30 mg/3 ml (10 mg/ml) (first)*
- *thiotepa injection recon soln 100 mg, 15 mg*
- TICE BCG INTRAVESICAL SUSPENSION FOR RECONSTITUTION 50 MG
- TIVDAK INTRAVENOUS RECON SOLN 40 MG
- *topotecan intravenous recon soln 4 mg*
- *topotecan intravenous solution 4 mg/4 ml (1 mg/ml)*
- *travasol 10 % intravenous parenteral solution 10 %*
- TRAZIMERA INTRAVENOUS RECON SOLN 150 MG, 420 MG
- TREANDA INTRAVENOUS RECON SOLN 100 MG, 25 MG
- *treprostinil sodium injection solution 1 mg/ml, 10 mg/ml, 2.5 mg/ml, 5 mg/ml*
- TRODELVY INTRAVENOUS RECON SOLN 180 MG

- TROPHAMINE 10 % INTRAVENOUS PARENTERAL SOLUTION 10 %
- UNITUXIN INTRAVENOUS SOLUTION 3.5 MG/ML
- *valrubicin intravesical solution 40 mg/ml*
- VARUBI ORAL TABLET 90 MG
- *vinorelbine intravenous solution 10 mg/ml, 50 mg/5 ml*
- XATMEP ORAL SOLUTION 2.5 MG/ML
- XGEVA SUBCUTANEOUS SOLUTION 120 MG/1.7 ML (70 MG/ML)
- YERVOY INTRAVENOUS SOLUTION 200 MG/40 ML (5 MG/ML), 50 MG/10 ML (5 MG/ML)
- YONDELIS INTRAVENOUS RECON SOLN 1 MG
- YUPELRI INHALATION SOLUTION FOR NEBULIZATION 175 MCG/3 ML
- ZALTRAP INTRAVENOUS SOLUTION 100 MG/4 ML (25 MG/ML), 200 MG/8 ML (25 MG/ML)
- ZANOSAR INTRAVENOUS RECON SOLN 1 GRAM
- ZEPZELCA INTRAVENOUS RECON SOLN 4 MG
- ZIRABEV INTRAVENOUS SOLUTION 25 MG/ML
- ZOLADEX SUBCUTANEOUS IMPLANT 10.8 MG, 3.6 MG
- ZYNLONTA INTRAVENOUS RECON SOLN 10 MG

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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